Medicare Prescription Drug Benefit Manual

Chapter 7 – Medication Therapy Management and Quality Improvement Program

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Note: This manual currently reflects CY 2007 guidance, and is subject to change for both periodic and annual updates.

10 – Medication Therapy Management and Quality Improvement Program

10.1 Introduction

Title 42 CFR Part 423, Subpart D, establishes the requirements Part D Plans must meet with regard to cost control and quality improvement under the Social Security Act (the Act). This chapter is divided into five main areas:

- Section 20 – Quality Assurance Requirements
- Section 30 – Medication Therapy Management Program (MTMP)
- Section 40 – Consumer Satisfaction Surveys
- Section 50 – Electronic Prescription Program (E-prescribing)
- Section 60 – Drug Utilization Management Section

10.2 Definition of Terms

For the purposes of this Manual the following definitions apply:

Dispenser—means a person or other legal entity licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located to provide drug products for human use by prescription in the course of professional practice.

Electronic media—means electronic storage media including memory devices in computers (hard drives), and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide open), extranet (using internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission.

We note that certain computer-generated faxes do not constitute true e-prescribing capability, but because these computer-generated transmissions started as an electronic version, they would qualify as electronic media. However, due to fears that the imposition of final e-prescribing standards would drive computer-generated faxers to revert to paper, CMS exempted those using computer-generated faxes from using the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard for transmitting prescriptions and prescription-related information. Section 42 C.F.R. 423.160(a)(3).

E-prescribing—means the transmission using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network.

E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser.

Electronic prescription drug program—means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals.

Prescriber—means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.

Prescription-related information—means information regarding eligibility for drug benefits, medication history, or related health or drug information for Part D eligible individuals

20 – Quality Assurance Requirements

Each Part D plan sponsor must establish quality assurance (QA) measures and systems to reduce medication errors and adverse drug interactions and improve medication use. The QA measures and systems include:

1. Representation that the plan sponsor requires network providers to comply with minimum standards for pharmacy practice as established by the States.
2. Concurrent drug utilization review systems, policies and procedures.
3. Retrospective drug utilization review systems, policies and procedures.
4. Internal medication error identification and reduction systems.
5. Provision of information to CMS regarding the plan sponsor's QA measures and systems, according to CMS-specified guidelines.

Furthermore, Part D plan sponsors must establish and maintain an electronic prescription drug program that is consistent with uniform e-prescribing standards that are adopted under 1860D-4(e)(3) of the SSA (see section 50 of this manual chapter for a description of the current e-prescribing standards). Prescribers, dispensers and plans must utilize the final e-prescribing standards when transmitting prescription and prescription-related information using electronic media for Part D covered drugs for Part D eligible individuals. While e-prescribing is voluntary for physicians (and other prescribers) and pharmacies (and other dispensers), if these persons or entities e-prescribe covered Part D drugs for Part D eligible individuals, they must comply with the adopted standards.

E-prescribing (addressed in section 50 of this chapter), although not required as an element of the sponsor's quality assurance system, has demonstrated value in preventing medication errors by permitting each prescription to be checked electronically for dosage, interactions with other medications, and therapeutic duplication, thereby improving medication use. Therefore, CMS recommends plan sponsors incorporate their electronic prescription drug program within their quality assurance system.

Additional elements that are not required in the sponsor's quality assurance system, but which CMS recommends plan sponsors consider for incorporation, include:

- Clinical decision support systems
- Educational interventions
- Bar codes
- Adverse event reporting systems
- Provider and patient education

20.1 – Compliance with State Standards

Plan sponsors are expected to require network providers to comply with minimum standards for pharmacy practice as established by the States. While CMS believes that current pharmacy practice standards established by the States provide applicable minimum standards for all pharmacy practice settings, we encourage plans and their network pharmacy providers to establish and agree upon additional quality assurance standards as necessary.

This policy is consistent with the Department of Health and Human Services' (DHHS) general position of deferring to States for regulating the practice of pharmacy. Therefore, plans should provide CMS with representation that their network providers are required to comply with minimum standards for pharmacy practice established by the States.

20.2 – Concurrent Drug Utilization Review

A Part D sponsor must have concurrent drug utilization review systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale or point of distribution.

The review must include, but not be limited to, the following:

- Screening for potential drug therapy problems due to therapeutic duplication
- Age/gender-related contraindications
- Over-utilization and under-utilization
- Drug-drug interactions
- Incorrect drug dosage or duration of drug therapy
- Drug-allergy contraindications
- Clinical abuse/misuse

20.3 – Retrospective Drug Utilization Review

A Part D sponsor must have retrospective drug utilization review systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate or medically unnecessary care among enrollees in a sponsor's Part D plan, or associated with specific drugs or groups of drugs.

Upon notification or discovery of an allegation of fraud, abuse or suspected pattern of inappropriate drug utilization, the Part D sponsor will review the case with the utmost concern to eliminate obvious billing or claims processing errors and, if necessary, direct the case to the appropriate authorities (i.e., Medic or local law enforcement). In such a case, Part D sponsors would provide prescriber and beneficiary education as appropriate. For instance, if a potential drug problem is discovered, intervention letters would be sent to all providers who ordered a drug relevant to the identified problem. An intervention might consist of an informational letter to the prescriber, a response form for the prescriber to complete, along with a pre-addressed return envelope, and a patient drug profile. Part D sponsors should not implement programs that decrease beneficiaries' access to their Part D benefit. This includes any sort of a "lock-in" program that limits beneficiaries to utilizing only a single pharmacy.

20.4 – Medication Error Identification and Reduction

While we currently do not require external medication error reporting, we do require plans to implement internal medication error identification and reduction systems as described in 42 CFR 423.153(c)(4). We are also requiring plans to provide us with information concerning their quality assurance measures and systems, in accordance with reporting requirements discussed in later sections of this chapter.

The National Coordinating Council for Medication Error Reporting and Prevention's definition of ''medication error,'' which the Food & Drug Administration proposed to adopt during rulemaking but never formally adopted, can serve as a guide for internal medication error identification and reduction systems. Plans may exercise the discretion to define medication error either more narrowly or more broadly than the description below. We expect plans to consider their internal control systems, current monitoring program and, ultimately, what is in the best interest of their plan members, in preventing medication errors.

> ''[A]ny preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.'' (See 68 FR 12500 (March 14, 2003)).

20.5 – Medwatch Reporting

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of marketed medical products, such as drugs and medical devices. In order to perform ongoing safety surveillance of medical products, the FDA relies on the voluntary reporting of serious adverse events, product quality problems and product use errors. FDA MedWatch enables healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use. Reporting can be done online, by phone, or by submitting the MedWatch 3500 form by mail or fax. We encourage plans to educate prescribers and pharmacy providers about the importance of reporting adverse events, product problems and product use errors, as well as how to utilize the FDA Medwatch reporting mechanisms. A broader discussion on Medwatch reporting, including downloadable Medwatch forms, is available at the following FDA Web page: http://www.fda.gov/medwatch.

20.6 – CMS Performance Measures

As we continue implementation of the Medicare prescription drug benefit, we are reviewing various data sources to identify the overall best plan performance measures. We believe that utilization of such measures will help to ensure our beneficiaries receive the highest quality prescription drug coverage and services. We also believe beneficiaries will want to consider these measures when deciding which Part D plan will best fit their individual prescription drug needs. To date, we have identified five key Part D plan performance domains that we believe will be the basis for evaluating plans' efficiency in providing quality prescription drug coverage. These five domains include customer service, complaints, appeals, data systems, and drug pricing. While these domains are broad and provide information about Part D sponsors across all operational functions, elements of each are integral in ensuring beneficiaries receive superior pharmacy care

services from the Part D sponsors. For instance, independent review entity (IRE) data will be used in conjunction with information from the complaints tracking module (CTM) and the sponsors' self reported appeals information to assess whether plan enrollees are obtaining access to the Part D drugs they need to sustain or improve their health. As additional analysis is completed, new measures or domains may be added. These data are being shared publicly via the Medicare Prescription Drug Plan Finder.

Apart from our own data systems, CTM, the Medicare Prescription Drug Plan Finder Tool, and Call Center statistics, we also currently require that Part D sponsors report on specific measures. These current measures are contained in the Final Medicare Part D Reporting Requirements, updated March 21, 2007 and are available on the CMS website at:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDReportingRequirements_CurrentYear.pdf.

The Final Medicare Part D Reporting Requirements specify certain data elements that must be reported by plan sponsors to CMS, as well as reporting timeframes. The quality-related categories of required data elements to be reported via the Health Plan Management System (HPMS) include:

- Medication Therapy Management Programs (MTMPs)
- Grievances
- Transition
- Appeals
- Call center operations.

Finally, we are committed to working with external stakeholders, such as the Pharmacy Quality Alliance, to establish industry wide strategies for measuring and reporting data that will help consumers make informed choices and appropriate healthcare decisions.

20.7 – Information for Quality Improvement Organizations (QIOs)

We expect that the QIOs will work with providers, practitioners, and plans to improve the quality of beneficiaries' medication therapies. The QIOs' goal is to improve quality of care, not to assign blame. They can assist each of these players to design systems to facilitate the delivery of quality care. Similarly, we expect that plans, as well as providers and practitioners, will be able to request technical assistance from QIOs to improve their MTMPs.

The QIOs are required to offer providers, practitioners, and Part D sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy, in accordance with contracts established with the Secretary.

Pursuant to section 1154(a)(14) of the Social Security Act, QIOs are required to review enrollees' written complaints about the quality of services they have received under the

Medicare program, as specified within the Social Security Act. For any complaint submitted to a QIO, the Part D sponsor should cooperate with the QIO in resolving the complaint. Upon completion of the investigation and resolution of the complaint with the Part D sponsor, the QIO will notify the beneficiary of the final disposition.

Information collected, acquired, or generated by a QIO in the performance of its responsibilities under 42 CFR 423.162 is subject to the confidentiality provisions of 42 CFR 480.

30 – Medication Therapy Management Program (MTMP)

30.1 – General Rule

A Part D sponsor must have established a MTMP that—

- Is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries, as described in section 30.2, are appropriately used to optimize therapeutic outcomes through improved medication use;
- Is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries;
- May be furnished by a pharmacist or other qualified provider; and
- May distinguish between services in ambulatory and institutional settings, while services and interventions may vary across setting, the criteria for identifying targeted beneficiaries eligible for MTMP cannot.

CMS believes that the standards and performance measures for MTM services currently in the marketplace are not sufficiently robust for purposes of setting more specific requirements for MTMP services and service level requirements under Part D. Therefore, plans must use their discretion to decide on which methods and which providers are best for providing MTMP services available under their specific MTMP. Initially, plans have the flexibility to design their MTMPs using any means. Services may be provided face-to-face, via the phone, via mail, via email, or any combination of these. As CMS works with industry to develop further measures and standards, and as certain methods for providing MTMP prove to be more effective, CMS may adopt standards that would require plans to offer more specific types of MTMP services that have been shown to be more effective.

Successful MTMPs will need to consider and coordinate not only the method of communication with targeted beneficiaries and the providers of services, but also other components such as the content of the service, the qualifications of the providers, the identification of targeted beneficiaries, and the documentation requirements associated with services performed.

Information related to Part D MTMP requirements is posted at:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/08.asp#TopOfPage

30.2 – Targeted Beneficiaries

Targeted beneficiaries for the MTMP as described in § 423.153(d)(1) are enrollees in the sponsor's Part D plan who—

1. Have multiple chronic diseases;
2. Are taking multiple Part D drugs; and
3. Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary.

The MMA provided a number of examples of multiple chronic conditions that could be targeted for MTMP, including diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure. Part D plans have significant flexibility however, in determining which populations are appropriate for medication therapy management.

Although plans decide how potential providers of MTM services are informed of MTM qualified beneficiaries, we envision that the most common method for identifying targeted beneficiaries to individuals responsible for providing the services (e.g. pharmacists), will be system edits, computerized notices that appear on the pharmacists' computer when a beneficiary fills a prescription. We expect that plans and pharmacists will coordinate these edits as part of the terms and conditions of their contracts. Plans need to develop appropriate mechanisms for identifying and notifying targeted beneficiaries who are eligible for MTMP services.

CMS has established an initial cost threshold of $4,000 as the level of annual costs beneficiaries are likely to have incurred to be eligible for participation in MTMPs as targeted beneficiaries.

If a plan chooses to offer MTM services to non-targeted beneficiaries, the plan should either:

1. Provide these MTM services to the beneficiary as value-added services using plan administrative funds. These services would have to meet all the requirements of value-added items and services as specified in the Part D Marketing Guidelines available at:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/MarketingGuidelines_11.01.05.pdf; or,

2. Notify the beneficiaries in advance that they are responsible for 100 percent of the cost involved in providing such services.

Regardless of the approach used, the costs for MTM services to non-targeted beneficiaries fall entirely outside the Part D cost sharing structure and do not count for purposes of tracking beneficiaries' total costs, out of-pocket costs, or for purposes of calculating reinsurance and risk sharing with Medicare.

Although participation in MTMPs is voluntary for beneficiaries, we hope they will participate to improve their therapeutic outcomes. Beneficiaries must not be denied access to prescription drugs based upon failure to participate in MTMPs.

30.3 – Use of Experts

MTMPs should be developed in cooperation with licensed and practicing pharmacists and physicians. Part D sponsors are expected to comply with State licensure requirements for pharmacy practice and ensure that network providers, where appropriate, are licensed accordingly.

30.4 – Considerations in MTMP Fees

An applicant to become a Part D sponsor must—

- Describe in its application how it takes into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing MTMP services for covered Part D drugs under a Part D plan.
- Disclose to CMS, upon request, the amount of the management and the portion paid for MTMP services to pharmacists and others upon request. Reports of these amounts are protected under the confidentiality provisions of section 1927(b)(3)(D) of the Act.

Individual plans determine fees associated with providing MTMPs, which may include services offered by pharmacists or other providers. Plans will have the flexibility to establish their own fees, but must take into account the time and resources associated with implementing the MTMP. CMS will require potential Part D sponsors to explain to us, as part of their application, how their fees account for the time and resources associated with their medication therapy management program.

CMS considers MTMP services provided to targeted beneficiaries as an administrative cost (included in the plan bid), incident to appropriate drug therapy, and not an additional benefit.

30.5 – MTMP Application

Each Part D sponsor is required to incorporate a MTMP into its plans' benefit structure. Annually, all Part D sponsors, including renewing sponsors and new applicants, must submit a MTMP description to CMS for review and approval. A CMS-approved MTMP is one of several required elements in the development of sponsors' bids for a contract year.

MA Private Fee for Service (MA-PFFS) organizations, as described in 42 CFR 422.4 (a)(3), are not required to have an MTMP. However, given that MA-PFFS organizations have an equal responsibility to provide a quality Part D product, CMS encourages MA-PFFS organizations to establish MTMPs to improve quality for their enrollees and to

submit their program to CMS for review. MA-PFFS organizations will be expected to meet the same standards as other Part D MTMPs and should expect to have their application evaluated accordingly.

The MTMP submission should be uploaded through the Health Plan Management System (HPMS) in the MTM submission module. One MTMP should be submitted per Contract ID. MTMP descriptions should be as detailed as possible, including policies and procedures, and submitted using the appropriate MTMP submission template. We expect to maintain the appropriate MTMP submission template for download through the HPMS MTM submission module. It will also be posted at:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/08.asp#TopOfPage.

CMS will communicate to each Contract via partd_mtm@cms.hhs.gov regarding the status of CMS's review of its MTMP (including whether the MTMP requires resubmission to correct deficiencies or if the MTMP meets all of the minimum requirements). If a Part D sponsor needs to submit an MTMP outside of the initial submission upload and resubmission processes, it should email a request to have the submission gate opened to partd_mtm@cms.hhs.gov. The following represents information the plans were required to submit as part of their applications for contract year 2008:

Information that MUST be included with the MTMP Application

- Criterion #1: Multiple Chronic Diseases
  - Provide the number of chronic diseases a beneficiary must have to meet this criterion. (Note: the definition of multiple is any 2 or more)
  - Provide the name of each chronic disease that applies.
  - Example: A beneficiary must have 2 out of 4 of the following chronic diseases - diabetes, asthma, heart failure, and hypertension.
- Criterion #2: Multiple Covered Part D Drugs
  - Provide the number of covered Part D drugs that a beneficiary must have filled to meet this criterion. (Note: the definition of multiple is any 2 or more)
  - Provide the type of covered Part D drugs that applies (i.e., chronic medications, all medications, disease-specific, etc.).
  - Example: A beneficiary must have filled any 5 or more distinct covered Part D drugs.
- Criterion #3: Part D drug cost of $4,000
  - Provide a detailed description of the analytical procedure used to determine if a beneficiary is **likely to incur** annual costs of at least $4,000 for all covered Part D drugs.
  - Example 1: Monthly or quarterly dollar threshold per beneficiary for covered Part D drugs.
  - Example 2: Certain drugs for high cost disease states.

    - Example 3: Predictive model used to identify beneficiaries who are likely to incur this annual cost.
- Procedure and frequency of identifying beneficiaries.
- Methods of enrollment and disenrollment.
- Type, frequency, and recipient of interventions.
- Who will provide MTM services? If using personnel outside of your company, describe how you take into account resources used and time required to provide the prescribed MTMP service.
    - Example: Number of FTEs, Type of staff (i.e., pharmacist), etc.
- How fees will be established for MTMP if using outside personnel. If establishing fees for pharmacists or others, provide the amount of fee respective to MTMP management and the fee paid for the provider of the MTM.
    - Example: $XXX per hour, per service, per diem, per member, etc.
    - If fees are covered as part of the services of the global PBM or vendor contract (without being priced out separately), note this in your submission. If the Plan is charged a fee by the PBM or vendor within the contract, then a description of the specific fees needs to be reported.
- Methods of documenting and measuring outcomes.
- Coordination with care management plans established for a targeted beneficiary under a Medicare Health Support Organization (MHSO), if applicable.

30.6 – MTMP Approval Considerations

During the MTMP approval process, we review the MTMP submission to ensure plans meet the following expectations:

- Beneficiaries will not be disenrolled from the MTMP program if they no longer meet one or more of the MTMP eligibility criteria as defined above, and will remain in the MTMP program for the remainder of the calendar year;
- The MTMP will serve and provide interventions for enrollees who meet all three of the required criteria, as defined above, regardless of setting (e.g., ambulatory, long term care, etc.);
- The MTMP will not include discriminatory exclusion criteria. If an enrollee meets all three of the required criteria as described by the Plan, the enrollee should be eligible for MTM intervention;
- The Plan will put into place safeguards against discrimination based on the nature of its MTM interventions (i.e., TTY if phone-based, Braille if mail-based, etc.).

An MTMP is based on the plan contract year. The plan's bid should take into account MTM costs for the applicable contract year, as MTMPs can change from year to year. As mentioned above, it is our expectation that once enrolled in the MTMP, beneficiaries will not be disenrolled if they no longer meet one or more of the MTMP eligibility criteria as defined by the Plan and will remain enrolled in the MTMP program for the remainder of

the calendar/contract year. This expectation, however, would not apply across contract years.

Beneficiaries must be re-targeted and meet the MTM eligibility criteria for enrollment each program year. For beneficiaries who continue to meet the eligibility criteria for the next contract year, enrollment in the MTMP may begin on the first of the year to avoid gaps in MTM services.

30.7 – Mid–Year MTMP Changes

Part D sponsors may have experiences during the current contract year that identify the need for changes to the current program year MTMP, or to the upcoming contract year program. CMS will allow certain changes to Part D sponsors' MTMP, if requested. All proposed Medication Therapy Management Program changes must be submitted to CMS for review and approval prior to the implementation of requested changes.

We have a 4 part policy regarding MTMP changes during the program year OR prior to the start of the upcoming program year.

1. Part D sponsors may make positive changes to the plan-designed eligibility criteria for multiple chronic diseases, multiple covered Part D drugs, or analytical procedures used to determine if a beneficiary is likely to incur annual costs in excess of a predetermined level as specified by the Secretary ($4,000 in CY 2007). These changes would make eligibility for the MTMP more inclusive and could increase the number of beneficiaries eligible to receive Part D MTM services. Positive changes may include:
   - Decreasing the minimum number of multiple chronic diseases.
   - Expanding the list of specific chronic diseases that apply.
   - Decreasing the minimum number of multiple covered Part D drugs.
   - Expanding the list of specific covered Part D drugs, or types of drugs, that apply.
2. Part D sponsors may make program enhancements or maintenance changes, including changes to:
   - Method of beneficiary enrollment/disenrollment or identification to increase or promote ease of beneficiary participation.
   - Expand the levels of intervention or services provided to participating targeted beneficiaries.
   - Methods of documenting and measuring outcomes.
3. Part D sponsors may make changes to the following:
   - The provider of MTM services.
   - Any fee schedules established for pharmacists and other MTM providers if using outside personnel. CMS will request that Part D sponsors disclose the newly established fees for outside personnel.

4. Part D sponsors may not make any negative changes to their MTMP. While the following list is not exhaustive, potentially negative changes include those that:
   - Promote discriminatory or exclusionary practices.
   - Decrease the number of enrollees eligible for MTM services.
   - Lower quality or robustness of MTM services.

All proposed MTMP changes must be submitted to CMS in the manner described below for review and approval prior to the implementation of requested changes. Part D sponsors must attest that any approved MTM marketing materials are not impacted by the proposed change or, alternatively, revised materials will be submitted and approved by CMS as necessary prior to implementation of the change.

Requests for MTMP changes during the program year may be submitted to CMS during the first 10 days of the last month of the quarter, starting with the second quarter. Specifically, requests may be made from March 1-March 10, June 1-June 10, and September 1-September 10. Requests should be submitted electronically to partd_mtm@cms.hhs.gov. The MTMP change request form should be completed and sent along with the entire (revised) MTMP in the same format as the program submitted for initial CMS approval. MTMP proposals are submitted using a template. Part D sponsors will receive an email correspondence regarding the approval of the MTMP change request. Part D plans must not implement such changes until they receive explicit notification of approval from CMS, and must not include any changes in marketing material until receiving explicit and affirmative CMS approval. Depending upon the number of submitted requests, plans should expect a response within 30 days.

Requests for changes to existing MTMPs that would be effective for an upcoming program year should be submitted to CMS between September 1 and September 10. Requests should be submitted electronically to partd_mtm@cms.hhs.gov. The MTMP change request form should be completed and sent along with the entire (revised) MTMP in the same format as the program submitted for initial CMS approval. MTMP proposals are submitted using a template. The Part D sponsor will receive an email correspondence regarding the approval of the MTMP change request.

Please refer to Appendix 1 for the MTMP Change Request form.

30.8 – MTMP Reporting

The requirements stipulating that Part D sponsors provide MTMP are described in 42 CFR 423.153. For monitoring purposes, Part D sponsors will be responsible for reporting several data elements related to their MTMP.

Data related to the identification of and participation by targeted beneficiaries in the MTMP will be submitted according to the following timeline (note: Period 2 encompasses one full year):

	Period 1	Period 2
Reporting Period	January 1 - June 30	January 1 - December 31
Data due to CMS/HPMS	August 31	February 29

Data elements to be entered into the HPMS at the Contract level.

1. The method used to enroll beneficiaries into the MTMP. Method of enrollment may be opt-in, opt-out, a combination of opt-in and opt-out, or other. This information will be reported using a selection from a drop-down box. If "other" is selected, a description will be required as a text field.
2. The number of beneficiaries who met the eligibility criteria for the MTMP in the specified time period above. This should be a numeric field.
3. The total number of beneficiaries who participated in the MTMP at any point during the time period specified above. This should be a longitudinally cumulative total, and be a subset of the number of beneficiaries who met the criteria for the MTMP in the specified time period. This should be a numeric field.
4. The total number of beneficiaries who discontinued participation from the MTMP at any time during the specified time period above. This should be a subset of the total number of beneficiaries who participated in the MTMP in the specified time period. This should be a numeric field.
5. The number of beneficiaries who discontinued participation from the MTMP due to death at any time during the specified time period above. This should be a subset of the total number of beneficiaries who discontinued participation from the MTMP in the specified time period. This should be a numeric field.
6. The number of beneficiaries who discontinued participation from the MTMP due to disenrollment from the Plan at any time during the specified time period above. This should be a subset of the total number of beneficiaries who discontinued participation from the MTMP in the specified time period. This should be a numeric field.
7. The number of beneficiaries who discontinued participation from the MTMP at their request at any time during the specified time period above. This should be a subset of the total number of beneficiaries who discontinued participation from the MTMP in the specified time period. This should be a numeric field.
8. The number of beneficiaries who declined to participate in the MTMP during the specified time period above. This should be a subset of the number of beneficiaries who met the criteria for the MTMP in the specified time period. This should be a numeric field.
9. For beneficiaries participating in the MTMP as of the last day of the reporting period specified, provide the prescription cost of all covered Part D medications on a per MTMP beneficiary per month basis. This should be a currency field, rounded to the nearest dollar. The numerator represents the total prescription

drug costs. The total prescription cost should be limited to covered Part D medications and be calculated using gross drug cost as follows: (Ingredient Cost Paid + Dispensing Fee + Sales Tax). This is based on the sum of all Part D covered prescriptions that were dispensed within the reporting period specified for each beneficiary participating in the MTMP as of the last day of the reporting period. This includes both MTMP beneficiary cost sharing and Part D costs paid by the Part D plan. The denominator represents the total number of member months for the MTMP participating beneficiaries. These member months should include all months enrolled in the Part D Contract during the reporting period specified, not only the months that the beneficiary enrolled in the MTMP.

The following equation also describes this calculation

$$\begin{bmatrix}\text{Total prescription cost}\\ \text{per MTMP beneficiary}\\ \text{per month}\end{bmatrix} = \frac{\sum_{i}^{n}\left(\sum_{\text{j}}^{\text{m}}(\text{Gross Drug Cost}\right)}{\sum_{i}^{n}\left(\begin{matrix}\text{Member Months in Part D Contract}\\ \text{during Reporting Period}\end{matrix}\right)}$$

{Gross Drug Cost = (Ingredient Cost Paid + Dispensing Fee + Sales Tax).

For beneficiaries i to n, and prescriptions j to m from the i^{th} beneficiary}

10. For beneficiaries participating in the MTMP as of the last day of the reporting period specified, provide the number of covered Part D 30-day equivalent prescriptions on a per MTMP beneficiary per month basis. This should be a numeric field.

    This numerator should be calculated by first summing days supply of all covered Part D prescriptions dispensed for beneficiaries participating in MTMP as of the last day of the reporting period, and dividing by 30 to determine the number of 30 day equivalent prescriptions dispensed. The denominator represents the total number of member months for the MTMP participating beneficiaries. These member months should include all months enrolled in the Part D Contract during the reporting period specified, not only the months that the beneficiary enrolled in the MTMP.

The following equation also describes this calculation:

$$\left[\begin{array}{c}\text{Total number of 30-day prescription equivalents} \\ \text{per MTMP beneficiary per month}\end{array}\right] = \frac{\sum_{i}^{n}\left(\sum_{j}^{m}\left(\frac{\text{Days Supply}}{30}\right)\right)}{\sum_{i}^{n}\left(\begin{array}{c}\text{Member Months in Part D Contract} \\ \text{during Reporting Period}\end{array}\right)}$$

{For beneficiaries i to n, and prescriptions j to m from the i^{th} beneficiary}

These MTMP reporting requirements are included in the 2007 Medicare Part D Reporting Requirements, and are available on the CMS website at:

www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDReportingRequirements_CurrentYear.pdf

30.9 – Exception for Private Fee-for-Service MA Plans

A private fee-for-service (PFFS) MA plan, as described in 42 CFR 422.4(a)(3), that offers qualified prescription drug coverage, is exempt from the requirement to establish a MTMP. However, as discussed in section 30.5, to the extent that an MA PFFS plan chooses to establish an MTMP, the MTMP will be expected to meet the same standards as are required for Part D MTMPs and the plan will have its MTMP proposal evaluated by CMS accordingly.

30.10 – Coordination with Care Management Plans

The Chronic Care Improvement Program, now referred to as Medicare Health Support, is a new program established by section 721 of the MMA, which added a new section (section 1807) to the Act. The new section 1807 creates a method for CMS to assist beneficiaries with multiple chronic conditions in managing their care.

A sponsor's MTMP must be coordinated with any care management plan established for a targeted individual enrolled in an MHSO. As part of this coordination, a Part D sponsor must provide drug claims data to MHSOs for those beneficiaries who are enrolled in MHSOs in a manner specified by CMS.

In an effort to assist plan sponsors with this requirement, and in addition to carrying out the provisions of §1807 of the Act, CMS will send prescription drug event (PDE) data to MHSOs on behalf of the Part D sponsor. To that end, we have prepared the attached Business Associate Agreement (see Appendix 2). We strongly encourage plan sponsors to sign the attached Business Associate Agreement so that CMS may share PDE data with the appropriate MHSO(s). Sponsors must ensure that the Business Associate Agreement is signed by a plan sponsor official able to bind the plan sponsor. Sponsors must also be certain to place their name in the definition of "Covered Entity" in the Business Associate Agreement. As a note, the information to be disclosed focuses on

utilization data and not drug cost data. Please refer to the definition of "prescription drug event data" in the Business Associate Agreement.

We note that Part D sponsors that fail to sign the attached Business Associate Agreement will still be bound by the regulations at 42 CFR 423.153(d) requiring certain exchanges of information with the MHSOs to exchange certain information with the MHSOs. Thus, Part D sponsors that fail to execute the Business Associate Agreement will be required to provide the requisite prescription drug event data directly to the appropriate MHSO(s), which includes an initial step where each PDP sponsor must provide retrospective information to each MHSO with monthly updates required thereafter (see section 30.10.1).

We note that in sharing the data, both the MHSO and the Part D sponsor will need to abide by the HIPAA privacy rules including transmitting only the minimum data necessary. We strongly encourage Part D plans to consult with their privacy counsel to ensure that the transmission of data complies with all aspects of the HIPAA privacy rules.

30.10.1 – Data sharing for plans that fail to sign the Business Associate Agreement

We expect that if a Part D sponsor fails to sign the Business Associate Agreement (see Appendix 2), the regulatory requirement to exchange data with MHSOs will be met as follows:

- Each MHSO will send an encrypted finder file to each relevant PDP sponsor containing only those MHSO beneficiaries that are, or have been previously, enrolled in that PDP.
- Upon receipt of the encrypted finder file, the sponsor will provide the relevant MHSO encrypted PDE data on all targeted beneficiaries, in the finder file, using the attached file layout (see Appendix 3). The encrypted PDE data will be provided in separate monthly files for each month from January 2006 through the most recent complete month. This set of monthly PDE data will be provided to each MHSO within four weeks of the sponsor receiving the initial finder file.
- Subsequent to the initial PDE data request, each MHSO will send a monthly encrypted finder file to each relevant sponsor containing only those MHSO beneficiaries that are, or have been, enrolled in the relevant sponsor so that the sponsor may then provide a monthly update to the MHSO.
- Each sponsor will provide to each MHSO the most recent complete month's encrypted PDE on all targeted beneficiaries, included in the monthly finder file, in the attached file format, within four weeks of receiving the monthly finder file from the applicable MHSO(s). The encrypted files should be forwarded to the appropriate MHSO on CD via common carrier, or via other secure means which the MHSO is able to receive
- If transmitted electronically, the prescription drug event data must be transmitted over a secure connection. Regardless of how the encrypted information is forwarded to the MHSO, the sponsor must comply with all applicable privacy and

security laws. For plan sponsors that do not execute the Business Associate Agreement, if there are issues with the transmission of information, the issues should be resolved between the plan sponsor and the particular MHSO. Furthermore, CMS will be monitoring any complaints relating to plan sponsors' compliance with this reporting requirement.

40 – Consumer Satisfaction Surveys

40.1 – General Rule

CMS will conduct consumer satisfaction surveys of enrollees of Part D plans in order to provide comparative information about qualified prescription drug coverage to enrollees as part of our information dissemination efforts. Section 1860D-4(d) of the Act specifies that these surveys be conducted in a manner similar to how they are conducted for MA plans. Accordingly, we will use the Consumer Assessment of Healthcare Providers and System (CAHPS) Survey process that we established for Part C at 42 CFR 422.152(b).

The purpose of the consumer satisfaction survey is to provide information in a timely manner for purposes of beneficiary plan choice which occurs during the fall of the year. We are still determining the timing for survey administration. There will be a separate survey process for the stand-alone PDPs which will follow the traditional process for MA plans in 2007. Because the purpose of the survey is to help consumers choose among the plan options, we have tried to focus, during the development process, on compiling information about issues that may vary across plans versus satisfaction with the overall benefit. Although plans must offer coverage that is at least actuarially equivalent to the defined standard benefit, there will be differences in formularies, customer service, informational materials, etc., and information on consumer satisfaction with a particular plan will be helpful to beneficiaries as they make their plan enrollment decisions for the coming year.

40.2 – Part D Plan Follow-up Responsibilities

Specific responsibilities for plan follow-up based upon survey results from CAHPS, once developed, will be described here.

50 – Electronic Prescription Program (E-prescribing)

50.1 – General Rule

The final e-prescribing standards that have been adopted thus far establish a framework from which a robust, interoperable e-prescribing environment can develop and grow. Section 101 of the Medicare Modernization Act (MMA) added section 1860D-4(e) to the Act to require that prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals that are transmitted electronically be transmitted in accordance with designated uniform standards. 42 CFR 423.160(a) requires Part D sponsors to establish and maintain an electronic prescription drug program that complies with those designated uniform standards when transmitting prescriptions and prescription-related information using electronic

media. Currently, this involves utilization of the "foundation standards" adopted as of January 2006.

The ASC X12N 270/271 Version 4010 and its version 4010A1 Addenda are the standard for transmitting eligibility inquiries and responses between Part D sponsors and prescribers. The NCPDP Telecommunication Standard Specification Version 5.1, and equivalent NCPDP Batch Standard Batch Implementation Guide Version 1.1 are the standard for transmitting eligibility inquiries and responses between dispensers and Part D sponsors. Plans are required to be able to provide prescribers and dispensers with eligibility and benefits information as well as other certain information with respect to the prescribing and dispensing of a covered Part D drug (such as medication history and information about the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed) in electronic form using the adopted standards.

Final e-prescribing standards were also adopted for certain transactions involving prescription or prescription-related information between prescribers and dispensers. These transactions must utilize the NCPDP SCRIPT version 5.0 standard, or the update to the adopted standard, version 8.1. The NCPDP SCRIPT standard allows for the communication of the key elements of the prescription between the prescribing physician and the dispenser, ultimately resulting in the beneficiary obtaining his/her medication at the pharmacy without ever receiving a paper prescription. This standard is described in greater detail in section 50.3 of this Chapter. While participation in e-prescribing is voluntary for the prescriber and dispenser, we expect that through the availability of adopted standards, more entities will seek out and embrace electronic prescribing.

Part D plans will also be responsible for complying with future e-prescribing standards promulgated subsequent to the completion of the 2006 e-prescribing pilot mandated by the MMA and the published CMS report to Congress in 2007. We expect that these additional final standards will enhance the capability of the e-prescribing process and improve quality of care for Part D eligible Medicare beneficiaries.

Except to the extent that the Drug Enforcement Agency (DEA) states otherwise, these e-prescribing rules do not apply to controlled drugs, even though such drugs may satisfy the definition of a Part D drug. Controlled drug substances remain under the jurisdiction of the DEA under the Controlled Substances Act. The Department of Health and Human Services and the DEA are working together to address the intersection of these regulations to ensure reliable standards are implemented across all prescribing environments.

50.2 – State Law Preemption

Section 1860D-4(e)(5) of the Act preempts State laws and regulations that are either contrary to the Federal standards or that restrict the ability to carry out (that is, stand as an obstacle to), the electronic prescription drug program requirements, and that also pertain to the electronic transmission of prescriptions or certain information regarding Part D drugs for Part D enrolled individuals. CMS had identified several categories of State

laws that are preempted in whole, or in part. These categories are intended to be examples and do not constitute an exhaustive list. Those categories of State laws that are preempted include:

1. State laws that expressly prohibit electronic prescribing.
2. State laws that prohibit the transmission of electronic prescriptions through intermediaries, such as networks and switches or pharmacy benefit managers (PBMs), or that prohibit access to such prescriptions by plans or their agents or other duly authorized third parties.
3. State laws that require certain language to be used, such as dispense as written, to indicate whether generic drugs may or may not be substituted, insofar as such language is not consistent with the adopted standard.
4. State laws that require handwritten signatures or other handwriting on prescriptions.

50.3 – Standards for E-Prescribing

The e-prescribing and the prescription drug program final rule published in the Federal Register on November, 7, 2005, (70 FR 67567) adopted three foundation e-prescribing standards with which Part D sponsors' e-prescribing programs must comply. We refer to them as "foundation standards" because they provide a foundation for e-prescribing implementation. These standards, for the specific electronic prescribing transactions outlined below, have not been subject to pilot testing under MMA due to the determination by the Secretary, in consultation with National Committee on Vital and Health Statistics (NCVHS), that there is adequate industry experience with these standards. However, these standards were included in the pilot project to test their interoperability with the initial standards that were to be tested. Pilot testing concluded on December 31, 2006. A report on the pilot test was issued to Congress in April 2007. The Foundation Standards are as follows:

1. Prescription standards.

   The NCPDP SCRIPT Standard, Implementation Guide, Version 5, Release 0, May 12, 2004 or the NCPDP SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

   - Get message transaction.
   - Status response transaction.
   - Error response transaction.
   - New prescription transaction.
   - Prescription change request transaction.
   - Prescription change response transaction.
   - Refill prescription request transaction.
   - Refill prescription response transaction.

- Verification transaction.
- Password change transaction.
- Cancel prescription request transaction.
- Cancel prescription response transaction.

Note: Although NCPDP SCRIPT 5.0 remains the adopted standard, the Secretary has recognized NCPDP SCRIPT Standard 8.1 as an update of the adopted standard. Accordingly, this subsequent version of the standards may be used on a voluntary basis in place of NCPDP SCRIPT 5.0 when use of that e-prescribing standard is required under the e-prescribing rules.

2. Eligibility standards.
   - For transmitting eligibility inquiries and responses between prescribers and Part D sponsors—

     The Accredited Standards Committee (ASC) X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, A1, October 2002, Washington Publishing Company, 004010X092A1.
   - For transmitting eligibility inquiries and responses between dispensers and Part D sponsors—

     The NCPDP Telecommunication Standard Specification, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, for the NCPDP Data Record in the Detail Data Record.

50.4 – Exemptions

1. Entities may use either Health Level 7 (HL7) messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity. If an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy), it must use the adopted NCPDP SCRIPT Standard or other applicable adopted standards. Any pharmacy within an entity must be able to receive electronic prescription transmittals for Medicare beneficiaries from outside the entity using the adopted NCPDP SCRIPT Standard.

   This exemption does not supersede any HIPAA requirement that may require the use of a HIPAA transaction standard within an organization. For further information on the HIPAA transaction standards, refer to 45 CFR 162, or the NCPDP or ASC Web sites at www.ncpdp.org or www.x12.org respectively.

2. Entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that, in turn, forwards the prescription to a dispenser, are exempt from the requirements to use the NCPDP SCRIPT Standard in transmitting such prescriptions or prescription-related information.

3. In accordance with section 1860D-4(e)(5) of the Act, the standards specified in 42 CFR 423.160(b) supersede any State law or regulation that—
   - Is contrary to the standards or restricts the ability to carry out Part D of Title XVIII of the Act; and
   - Pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under Part D of Title XVIII of the Act.

4. Entities transmitting prescriptions or prescription-related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard in transmitting such prescriptions or prescription-related information.

50.5 – Promotion of Electronic Prescribing by MA-PD Plans

An MA organization offering an MA-PD plan may provide for a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with the electronic prescription standards established in the Federal regulations at 42 CFR 423.160(b). Any payments must be in compliance with applicable Federal and State laws related to fraud and abuse, including the physician self-referral prohibition (section 1877 of the Act), and the Federal anti-kickback statute (section 1128B(b) of the Act), and incentives must not inappropriately influence physician prescribing patterns.

60 – Drug Utilization Management Program

A Part D sponsor must establish a reasonable and appropriate drug utilization management program that—

- Maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications;
- Provides CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS; and,
- Includes incentives to reduce costs when medically appropriate.

Common utilization management tools include formularies, prior authorization requirements, and promotion of lower cost generics. CMS issued separate formulary

guidance on these tools in Chapter 6 of the *Prescription Drug Benefit Manual*: *Part D Drugs and Formulary Requirements*.

60.1 – Over-the-Counter Drugs as Part of Utilization Management Programs

Health plans and pharmacy benefit managers currently provide targeted coverage of over-the-counter medications (OTCs) in the commercial market as part of their cost-reduction strategies. OTCs, many of which (e.g., Prilosec OTC® and Claritin®) were available by prescription when first marketed, may offer significantly cheaper alternatives to branded prescription medications, and often work just as well for most patients. The Medicare Modernization Act (MMA) of 2003 does not allow Medicare plans to include OTCs as part of their drug benefit or supplemental coverage. However, effective with the 2007 benefit coverage year, CMS allows Medicare plans the option to provide this alternative as part of their administrative cost structure not solely limited to approved step-therapy protocols.

CMS will continue to review and approve plans' specific OTC protocols shown to provide safe, effective and less costly alternatives. While the potential cost savings associated with using certain OTCs is significant, CMS does not believe many OTC products will offer such savings.

In certain situations, OTCs may be included as part of a step-therapy program, but plans are no longer limited to this option. However, if a plan includes OTC products as a part of its broader utilization management strategy, the plan may only require prior authorization or otherwise limit dispensing of formulary alternatives if such limitation is readily resolvable at the point of sale. Should beneficiaries decide that they do not want to take advantage of the zero cost OTCs, they must be provided access to the prescription product or formulary alternative the physician has prescribed for them.

Without exception, OTCs included as part of a cost-effective drug utilization management program must be provided to the beneficiary without any direct cost-sharing at the point of sale (costs would be included in the administrative portion of the bid and, thus, ultimately reflected in premiums).

Plans choosing to include OTC products within their utilization management programs should understand and be prepared to appropriately educate their enrollees on the difference between OTCs, provided as part of the administrative costs component of the plan benefit, as opposed to covered Part D drugs. Although beneficiaries will (and must) enjoy no direct cost-sharing on these OTCs, they will not have the same beneficiary protections required to ensure appropriate access to Part D drugs. For example, if a plan changes its utilization management program to substitute one OTC agent for another, beneficiaries would not have meaningful exceptions or appeals options to remain on the original OTC agent. (This does not affect enrollees' ability to pursue an exception or appeal of a step-therapy requirement where the plan requires the enrollee to use an OTC

agent prior to covering a Part D drug. The enrollee could pursue an exception or appeal in order to directly access the prescription drug without trying the OTC drug first.)

60.2 – Exception for Private Fee-for-Service MA Plans

A private fee-for-service (PFFS) MA plan, as described in 42 CFR 422.4(a)(3), that offers qualified prescription drug coverage, is exempt from the requirement to establish a drug utilization management program. If a PFFS MA plan elects to implement a drug utilization management program, they must comply with all of requirements contained in this chapter.

Appendix 1

Medication Therapy Management Program (MTMP)
Change Request Form

- This change request form should be used to communicate Medication Therapy Management Program (MTMP) changes to CMS for review.
- Completed change request forms should be emailed to partd_mtm@cms.hhs.gov.
- The entire (revised) MTMP should be submitted for review along with the change request form. The MTMP should be submitted in the same format as the program submitted for initial CMS approval. Beginning for program year 2007 submissions, MTMP proposals were submitted using a template.
- Part D Sponsors should attest that any approved MTM marketing materials are not impacted by the proposed change or such marketing materials will be submitted and approved by CMS as necessary prior to implementation of the change.

Contract ID(s):

Organization Name:

MTMP Main Contact Name:

MTMP Main Contact Phone Number:

MTMP Main Contact Email Address:

MTMP Program Year (yyyy):

Effective date of MTMP change (mm/dd/yyyy):

Within the appropriate section, provide a brief description and reason for the MTMP change requested:

Section	**Brief description of MTMP change and reason**
Eligibility Criteria	
Identification	
Method of enrollment or disenrollment	
Interventions	
Provider of MTM services/ Resources:	
Fees	
Outcomes	
Other	

I attest that the following change(s) either do not impact approved MTM marketing materials or such marketing materials will be submitted and approved by CMS as necessary prior to implementation of the change.

(Name) (Title) (Date)

Appendix 2

Business Associate Agreement

These Business Associate Provisions ("Agreement") are attached to the Contract with Approved Entity Pursuant to Sections 1860D-1 through 1860D-42 of the Social Security Act for the Operation of a Voluntary Medicare Prescription Drug Plan and are effective _____, 200_ ("Effective Date"), by and between Business Associate and Covered Entity, as defined in Section 1 (each a "party" and together "the parties").

The parties agree as follows.

1. Definitions:

All terms used herein and not otherwise defined shall have the same meaning as in the HIPAA Administrative Simplification provisions, including the Privacy and Security Rules (45 CFR Parts 160, 162 and 164).
"Business Associate" (BA) shall mean the Center for Beneficiary Choices in the Centers for Medicare & Medicaid Services when it performs the function of disclosing protected health information (PHI) included in prescription drug event data on behalf of the Covered Entity, for the purposes of performing the health care operations required under section 1807 of the Social Security Act (42 U.S.C. § 1395b-8) (requiring the Secretary to establish a chronic care improvement program designed to improve clinical quality and beneficiary satisfaction and achieve spending targets for certain targeted beneficiaries under the Act).

"Covered Entity" (CE) shall mean the [Insert Name of Prescription Drug Plan Sponsor].

"Electronic Protected Health Information" (ePHI) shall have the same meaning as the term "electronic protected health information" in 45 C.F.R. § 160.103, limited to the information created or received by BA from or on behalf of CE. For purposes of this Agreement, ePHI will include only the ePHI that is included in prescription drug event data that is used for purposes of complying with section 1807 of the Social Security Act (42 U.S.C. § 1395b-8).

"HIPAA" is the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191.

"Individual" shall have the same meaning as the term "individual" in 45 CFR § 160.103, except that this term includes such person(s) who qualify as a personal representative in accordance with 45 CFR164.502(g).

"Prescription drug event data" (PDE data) is the information submitted by each Part D sponsor in accordance with the rules in 42 CFR 423.322 for each prescription drug

claim. The PDE data is a summary record that documents the final adjudication of a dispensing event. The document, "Instructions. Requirements for Submitting Prescription Drug Event Data", issued April 26, 2006 (and as updated or amended), lists the required set of data elements for all PDE records.

These data include:

- Identification of the Part D sponsor and Part D plan through contract number and plan benefit package identification number.
- Health insurance claim number, which identifies the particular beneficiary receiving the prescription.
- Patient date of birth and gender.
- Date of service.
- Date paid by the plan.
- Identification of pharmacy where the prescription was filled.
- Service provider identification qualifier.
- Identification of prescribing health care professional.
- Prescriber identification qualifier.
- Identification of dispensed product.
- National Drug Code number, Health Related Item Code or Uniform Product Code.
- Indication of whether drug was compounded or mixed.
- Indication of prescriber's instruction regarding substitution of generic equivalents or order to "dispense as written."
- Quantity dispensed (for example, number of tablets, grams, milliliters, or other unit).
- Days supply.
- Fill number.
- Dispensing status and whether the full quantity is dispensed at one time, or the quantity is partially filled.

"Protected Health Information" (PHI) shall have the same meaning as the term "protected health information" in 45 C.F.R. § 160.103, limited to the PHI created or received by BA from or on behalf of CE. For purposes of this Agreement, PHI will include only the PHI that is included in PDE data that is used for purposes of complying with section 1807 of the Social Security Act (42 U.S.C. § 1395b-8).

"Secretary" shall mean the Secretary of the Department of Health and Human Services or the Secretary's designee.

"Security incident" shall have the same meaning as the term "security incident" in 45 CFR 164.304.

"Required by Law" shall have the same meaning as the term "required by law" in 45 CFR 164.103.

2. Obligations and Activities of BA:

(a) BA agrees to not use or disclose PHI included in PDE data created or received by BA from or on behalf of CE other than as permitted or required by this Agreement or applicable law.

(b) BA agrees to use appropriate safeguards to prevent use or disclosure of PHI included in PDE data created or received by BA from or on behalf of CE, unless the disclosure is otherwise provided for by this Agreement and/or permitted by law. Furthermore, BA agrees to use appropriate administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the ePHI included in PDE data it creates, receives, maintains or transmits on behalf of the CE to prevent unauthorized use or disclosure of such ePHI.

(c) BA agrees to mitigate, to the extent practicable, any harmful effect that is known to BA of a use or disclosure of PHI included in PDE data by BA in violation of the requirements of this Agreement.

(d) BA agrees to report to CE any use or disclosure involving PHI included in PDE data that is not provided for by this Agreement and/or permitted by law, of which it becomes aware. Furthermore, BA agrees to report to CE any security incident involving ePHI included in PDE data of which it becomes aware.

(e) BA agrees to require that any agent, including a subcontractor, to whom it provides PHI included in PDE data received from CE, or created or received by BA on behalf of CE, agrees to the same restrictions and conditions that apply through this Agreement to BA with respect to such information.

(f) BA agrees to document such disclosures of PHI included in PDE data, and information related to such disclosures, as would be required for CE to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR 164.528.

(g) BA agrees to provide to CE, or an individual identified by the CE information collected under this Agreement, to permit CE to respond to a request by an Individual for an accounting of disclosures of PHI included in PDE data, in accordance with 45 CFR 164.528.

3. Permitted Uses and Disclosures by BA:

(a) Except as otherwise limited in this Agreement, BA may use or disclose PHI included in PDE data, on behalf of or to provide services to CE, for purposes of implementing and maintaining Medicare Health Support Organizations (MHSOs), which help chronically ill beneficiaries stay healthier, accelerate the adoption of health information technology, reduce avoidable costs, and diminish health disparities among Medicare beneficiaries nationally, provided that such use or disclosure of PHI included in PDE data would not violate the HIPAA Privacy or Security Rules if done by CE. These uses and disclosures include:

(1) Using and disclosing PDE data to support the development, testing, evaluation and implementation of MHSOs (Section 1807 of the Social Security Act, 42 U.S.C. §1395b-8); and

(2) Submitting available data on applicable Part D enrollees to MHSOs on a monthly basis.

(b) Except as otherwise limited in this Agreement, BA may use PHI included in PDE data for the proper management and administration of the BA or to carry out the legal responsibilities of the BA, and may disclose PHI included in PDE data to a third party for the same purposes, provided that the disclosures are permitted by law or BA has received from the third party legally binding written assurances that (i) the information will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the third party; and (ii) the third party will notify BA of any instances of which it becomes aware in which the confidentiality of the information has been breached.

(c) BA may use PHI included in PDE data to report violations of law to appropriate Federal and State authorities, consistent with 45 C.F.R. § 164.502(j)(1).

(d) BA agrees to provide to CE, at the CE's request, any PHI included in PDE data that is received or created on behalf of CE so long as CE's intended use or disclosure of that PHI is permitted by the Privacy Rule and consistent with the CE's Notice of Privacy Practices.

4. Obligations of CE:

(a) CE shall notify BA of any limitation(s) in its notice of privacy practices of CE in accordance with 45 CFR 164.520, to the extent that such limitation may affect BA's use or disclosure of PHI included in PDE data.

(b) CE shall notify BA of any changes in, or revocation of, permission by Individual to use or disclose PHI included in PDE data, to the extent that such changes may affect BA's use or disclosure of PHI under this Agreement.

(c) CE shall notify BA of any restriction to the use or disclosure of PHI included in PDE data that CE has agreed to in accordance with 45 CFR 164.522, to the extent that such restriction may affect BA's use or disclosure of PHI under this Agreement.

5. Permissible Requests by CE:

CE shall not request BA to use or disclose PHI included in PDE data in any manner that would not be permissible under the HIPAA Privacy or Security Rules if done by the CE.

6. Term of Provision:

(a) The term of this Agreement shall be effective as of the signing of this Agreement by both parties**,** and shall terminate when all of the PHI provided by CE to BA, or created or received by BA on behalf of CE, is no longer being provided to MHSOs and is either destroyed or returned to BA, or, if it is infeasible to return or destroy PHI, protections are extended to such information, in accordance with the termination

provisions in this Section.(b) Termination for Cause. Upon CE's knowledge of a material breach by BA, CE shall either:

(1) Provide an opportunity for BA to cure the breach or end the violation and terminate this Agreement if BA does not cure the breach or end the violation within the time specified by CE;

(2) Immediately terminate this Agreement if BA has breached a material term of this Agreement and cure is not possible; or

(3) If neither termination nor cure are feasible, CE shall report the violation to the Secretary.

(c) Termination of this Agreement:

(1) Upon termination of this Agreement, for any reason, BA shall discontinue providing PHI included in PDE data, pursuant to Section 3, received from CE, or created or received by BA on behalf of CE. This provision shall apply to PHI included in PDE data that is in the possession of subcontractors or agents of BA. Entities described in Section 3 shall retain no copies of the PHI.

(2) In the event that BA determines that it is infeasible for the entity or entities described in Section 3 to return or destroy PHI included in PDE data, BA shall extend the protections of Section 2 of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as the entity or entities described in Section 3 maintain such PHI.

7. Miscellaneous:

(a) A reference in this Agreement to a section in the Rules issued under HIPAA means the section as in effect or as amended.

(b) The Parties agree to take such action in good faith as is reasonably necessary to amend this Agreement from time to time as is necessary for CE to comply with the requirements of the Rules issued under HIPAA.

(c) The respective rights and obligations of BA under Section 6(c)(2) and this Section 7(c) shall survive the termination for any reason of this Agreement.

(d) Any ambiguity in this Agreement shall be resolved to permit CE to comply with the Rules implemented under HIPAA.

(e) Nothing in this Agreement shall confer upon any person, other than the parties and their respective successors and assigns, any rights, remedies, obligations or liabilities whatsoever.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

By: _____	***By: _____***
Print Name: _____	***Print Name: _____***
Print Title: _____	***Print Title: _____***
Date: _____	***Date: _____***

Appendix 3

PDE File Layout for MHSO

Field #	Field Name	Position	Format	Length	Description/Value
1	FILLER	1 – 50	Alphanumeric	50	SPACES
2	ADJUSTMENT DELETION CODE	51 – 51	Alphanumeric	1	A = Adjustment D = Deletion Blank = Original PDE C = Credit
3	DISPENSING STATUS CODE	52 – 52	Alphanumeric	1	Blank = Not Specified 'P' = Partial Fill 'C' = Completion of Partial Fill
4	RX CLAIM CONTROL NUMBER	53 – 92	Alphanumeric	40	A number assigned by the Plan to identify the prescription drug event
5	RX CARDHOLDER IDENTIFIER	93 – 112	Alphanumeric	20	Plan identification of the enrollee. Assigned by plan.
6	RX SERVICE REFERENCE NUMBER	113 – 121	Numeric	9	The field length is 9 to accommodate proposed future NCPDP standard. Under 5.1, right justify and fill with 2 leading zeros. When plans compile PDEs from non-standard formats, the plans must assign a unique reference number if necessary. A reference number must be unique for any DOS and Service Provider ID combination.
7	RX SERVICE DATE (DOS)	122 – 129	Numeric	8	CCYYMMDD
8	FILL NUMBER	130 – 131	Numeric	2	Values = 0 - 99. If unavailable, use 0.
9	HEALTH INSURANCE CLAIM NUMBER (HICN)	132 – 151	Alphanumeric	20	Medicare Health Insurance Claim Number (HICN) or Railroad Retirement Board (RRB) number.
10	FILLER	152 – 153	Alphanumeric	2	SPACES
11	PATIENT DATE OF BIRTH (DOB)	154 – 161	Numeric	8	CCYYMMDD
12	PATIENT GENDER	162 – 162	Numeric	1	1 = M 2 = F Unspecified or unknown values are not accepted.
13	FILLER	163 – 184	Alphanumeric	22	SPACES

4 **Field # Field Name Position Format Length Description/Value**

14	COMPOUND CODE	185 – 185	Numeric	1	0 = Not a compound 1 = Compound (single) 2 = Compound (multiple)
15	DISPENSE AS WRITTEN (DAW) PRODUCT SELECTION CODE	186 – 186	Alphanumeric	1	0 = No Product Selection Indicated 1 = Substitution Not Allowed by Prescriber 2 = Substitution Allowed - Patient Requested Product Dispensed 3 = Substitution Allowed - Pharmacist Selected Product Dispensed 4 = Substitution Allowed - Generic Drug Not in Stock 5 = Substitution Allowed - Brand Drug Dispensed as Generic 6 = Override 7 = Substitution Not Allowed - Brand Drug Mandated by Law 8 = Substitution Allowed - Generic Drug Not Available in Marketplace 9 = Other
16	QUANTITY DISPENSED	187 – 196	Amount 9(7)V999	10	Number of units, grams, milliliters, other. If compounded item, total of all ingredients will be supplied as Quantity Dispensed. Partial fill quantities should be submitted for the prescribed quantity. The co-pay should be collected in full and the remaining quantity should be provided to the beneficiary as soon as possible.
17	FILLER	197 – 197	Alphanumeric	1	SPACE
18	DAYS SUPPLY	198 – 200	Numeric	3	0 – 999
19	CATASTROPHIC COVERAGE CODE	201 – 201	Alphanumeric	1	A = Attachment Point C = Above Attachment Point Blank = Attachment Point Not Met
20	NON-STANDARD FORMAT CODE	202 – 202	Alphanumeric	1	Format of claims originating in a non-standard format. X = X12 837 B = Beneficiary submitted claim P = Paper claim from provider Blank = NCPDP electronic format
21	PAID DATE	203 – 210	Numeric	8	CCYYMMDD. The date the plan paid the pharmacy for the prescription drug.

5 **Field # Field Name Position Format Length Description/Value**

22	RX PRICE EXCEPTION CODE	211 – 211	Alphanumeric	1	An indicator to identify claims where normal pharmacy/plan pricing agreements are not applicable. Examples include out-of-network pharmacies, situations where Medicare is not the primary payer, etc. Values: M - Medicare is a Secondary Payer O - Out of Network Pharmacy Blank - No data available
23	DRUG COVERAGE STATUS CODE	212 – 212	Alphanumeric	1	Coverage status of the drug under part D and/or the PBP. C = Covered E = Supplemental drugs (reported by Enhanced Alternative plans only) O = Over-the-counter drugs
24	PRODUCT SERVICE ID	213 – 231	Alphanumeric	19	NDC, HRI or UPC codes. Fill the first 11 positions, no spaces or hyphens, followed by 8 spaces. Format is NNNNNDDDDPP. DDPS will reject the following billing codes for compounded legend and/or scheduled drugs: 99999999999, 99999999992, 99999999993, 99999999994, 99999999995, 99999999996.
25	SERVICE PROVIDER ID	232 – 246	Alphanumeric	15	When plans report Service Provider ID Qualifier = ‘99’ - Other, populate Service Provider ID with the default value PAPERCLAIM defined for TrOOP Facilitation Contract. When plans report Federal Tax Number (TIN), use the following format: ex: 999999999 (do not report embedded dashes).
26	SERVICE PROVIDER ID QUALIFIER	247 – 248	Alphanumeric	2	The type of pharmacy provider identifier used in field 13. ’01’ = National Provider Identifier (NPI) ’06’ = UPIN ’07’ = NCPDP Number ’0’8 = State License ’11’ = Federal Tax Number (TIN or EIN) ’99’ = Other Values of ‘06’, ‘08’, ‘11’, or ‘99’ only acceptable if non-standard format = B, X or P.

6 **Field # Field Name Position Format Length Description/Value**

27	PRESCRIBER ID	249 – 263	Alphanumeric	15	Prescriber DEA number or State License Number. CMS will use NPI in this field when the NPI is implemented. Covered entities must comply by May 24, 2007. Small plans must comply by May 24, 2008.
28	PRESCRIBER ID QUALIFIER	264 – 265	Alphanumeric	2	The type of Prescriber identifier used in field 22. 01 = National Provider Identifier (NPI when implemented) 06 = UPIN 08 = State License Number 12 = Drug Enforcement Administration (DEA) number
29	FILLER	266 – 273	Alphanumeric	8	SPACES
30	Plan Contract Number	274 – 278	Alphanumeric	5	A unique number assigned by CMS to the Contract between CMS and an organization that offers prescription drug coverage under a plan.
31	Plan Benefit Package Number	279 – 281	Alphanumeric	3	A unique number assigned to identify a specific prescription