DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR BENEFICIARY CHOICES

December 1, 2006

Memorandum To: All Part D plans

Subject: Medicare Part D Manual – Draft of Chapter 7

From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

Today we are releasing for comment the draft of Chapter 7 of the Medicare Part D Manual. The draft of Chapter 7 consolidates previous guidance, questions and answers, and HPMS memos. In particular, the revised draft contains information specific to the following areas:

- Quality Assurance Requirements
- Medication Therapy Management
- E-prescribing
- Drug Utilization Management

Comments on the draft of Chapter 7 must be received by CMS no later than 5:00 p.m. EST, Friday, December 15, 2006. Comments must be submitted via e-mail at PartDBenefitImpl@cms.hhs.gov. Please include ***Chapter 7*** in the subject line of the email. If you have questions contact Greg Dill (312) 353-1754.

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 – Introduction

Title 42 CFR Part 423, Subpart D, "Cost Control and Quality Improvement Requirements for Part D Plans," establishes the requirements Part D plans must meet under the Social Security Act (the Act). This chapter is divided into six main areas:

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

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.

Further, the final regulations establishing the e-prescribing standards require that Part D plan sponsors establish and maintain an electronic prescription drug program that complies with certain adopted standards (see section 60 of this manual for a description of these standards) when transmitting prescription and prescription-related information

using electronic media 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 must 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.

Deferring to existing authority for regulating pharmacy practice is consistent with the DHHS' general position of deferring to States for regulating the practice of pharmacy. Therefore, plans must 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.

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 § 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.

The following description of ''medication error'', which was proposed during rulemaking, but not 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.

> ''Any 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

FDA has the responsibility for assuring the safety and efficacy of all regulated marketed medical products. MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems and product use errors with human medical products, such as drugs and medical devices. Medwatch allows 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 on line, by phone, or by submitting the MedWatch 3500 form by mail or fax.

We encourage plans to utilize the FDA Medwatch 3500 form for reporting adverse events, as well as educating prescribers and pharmacy providers about its availability. A broader discussion on Medwatch reporting, as well as downloadable Medwatch forms, is available at the following FDA webpage: http://www.fda.gov/medwatch/ .

20.6 – CMS Performance Measures

With the ongoing implementation of the Drug Benefit we are reviewing various data sources for identification of the overall best plan performance measures. We believe that utilization of such measures will ensure our beneficiaries receive the highest quality best prescription drug coverage and services. We also believe beneficiaries will want to consider these measures when deciding on 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, exceptions and appeals, data systems, and pricing. While these domains are broad and provide information about the Part D sponsor across all systems, elements of each are integral in ensuring the beneficiary receives superior pharmacy care services from the Part D Sponsor. For instance, independent review entity (IRE) data will be used in conjunction with information from the complaints tracking system (CTM) and the Sponsor's self reported appeals information to access if the beneficiary is obtaining access to the Part D drugs they need to sustain or improve their health. While we are just beginning to evaluate these domains in conjunction with the initial data, we plan on issuing further guidance in this area for plans to understand the domains and their respective elements and how they can use these metrics to improve their overall plan performance.

Apart from our own data systems, CTM, Medicare Prescription Drug Plan Finder Tool, and Call Center statistics, we currently require that Part D Sponsors also report on specific measures. These current measures are contained in the Final Medicare Part D Reporting Requirements, dated April 18, 2005, updated January 25, 2006 and are available on the CMS website at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDReportingRequirements_CurrentYear.pdf.

The file specifies certain data elements that need to be reported by plan sponsors and the reporting timeframes to CMS. The categories of required data related to quality to be reported via the Health Plan Management System include:

- MTMPs,
- Grievances,
- Drug utilization management,
- Appeals, and
- Call center operations.

These data categories are addressed in greater detail in specific sections of this manual chapter.

Finally, we are committing to work with outside alliances, such as the Pharmacy Quality Alliance, which are working 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 (QIO)

We expect that the QIOs will work with physicians, pharmacists, 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 of care. Similarly, we expect that both plans and pharmacies will be able to request technical assistance from QIOs to improve their MTMPs.

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.

Our final regulations also require that QIOs must 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 must cooperate with the QIO in resolving the complaint. Upon completion of 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 this section is subject to the confidentiality provisions of 42 CFR Part 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 as described;
- 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 MTMP eligibility criteria cannot.

CMS believes that existing standards and performance measures are insufficient to support further specification for MTMP services and service level requirements, and therefore plans need the 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 medication therapy management programs using any means. Services could be provided face-to-face, via the phone, via mail, via email, or any combination of these. However, as CMS works with industry to develop further measures and standards, and if 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 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.

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 for MTMP, including diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure. Part D plans however have significant flexibility in determining which populations are appropriate for medication therapy management.

Although plans decide if and how providers and beneficiaries can participate in identifying targets, 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. Successful MTMPs must be coordinated and plans need to develop appropriate mechanisms for notifying and identifying targeted beneficiaries who are eligible for MTMP services.

CMS has established the level of annual costs, likely to be incurred for covered part D drugs by an enrollee, which will serve as a cost threshold for medication therapy management programs. The initial cost threshold is set at $4,000 and remains at this level for 2007.

If a plan chooses to offer MTM services to non-targeted beneficiaries, the plan must 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 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

The MTMP must be developed in cooperation with licensed and practicing pharmacists and physicians. Part D sponsors must 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 dispensing fees and the portion paid for MTMP services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

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

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

30.5 – MTMP Application

In years past the Plan's MTMP submission was an element of the Part D Sponsors application process. In CY 2008 and years forward we are considering the creation of a separate HPMS submission process that would not necessarily be linked to the Part D Sponsors Application. We anticipate that this new module will include an input form for interface with HPMS and will provide plans the ability to upload their MTMP file through this form. Even though this new functionality may be separate from the application, no Plan, other than PFFS, will be able to complete the contracting process without obtaining an approved MTMP by CMS.

While we expect the physical MTMP Application to change in CY2007, the essential elements of the application will not. The following represents information the plan must be prepared to submit as part of their application in 2007:

Information that MUST be included with the MTMP Application

Criteria #1: Multiple Chronic Diseases

- Provide the number of chronic diseases a beneficiary must have to meet this criteria.
- Please 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.

Criteria #2: Multiple Covered Part D Drugs

- Provide the number of covered Part D drugs that a beneficiary must have filled to meet this criteria.
- Please 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.

Criteria #3: Part D drug cost of $4,000

- Provide a 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 drug

● Example 2: Certain drugs for high cost disease states.

Description of MTMP, such as, but not limited to:

● Procedure and frequency of identifying beneficiaries
● Methods of enrollment/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 establishing fees for pharmacists or others, provide the amount of management, dispensing fees, or other payment.

- Example: $XXX per hour, per service, per diem, etc.

● Methods of documenting and measuring outcomes
● Coordination with care management plans established for a targeted beneficiary under a chronic care improvement program

The current MTM submission and application documents can be found on our Plan Oversight and Reporting Webpage at the following location: http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp#TopOfPage . As we move to the new MTMP application and submission process we will provide more information for CY2008.

30.6 – MTMP Approval Considerations

There are a number of expectations we ensure plans meet during the MTMP approval process.

- A beneficiary 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 your plan, the enrollee should be eligible for MTM intervention,
- The Plan will put into place safeguared against discrimination based on the nature of your MTM interventions (i.e. TTY if phone based, Braille if mail based, etc.).

30.7 - Mid-Year MTMP Changes

CMS will allow certain changes to Part D Sponsors' MTMP, if requested. 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. 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 the eligibility 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 that include changes to:
    - Method of beneficiary enrollment/disenrollment or identification to increase or promote ease of beneficiary participation.
    - Expand the levels of intervention or service 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 changes that:
    - Promote discriminatory or exclusionary practices.
    - Decrease the number of enrollees eligible for MTM Services
    - Lower quality or robustness of MTM services

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

MTMP requests for 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. Beginning for contract year 2007, MTMP proposals are submitted using a template. If one MTMP change request applies to multiple contract IDs, one change request form and attached program may be submitted which lists all applicable contract IDs.

Part D Sponsor's 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 submit any changes to 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. Beginning for contract year 2007, MTMP proposals were submitted using a template. If one MTMP change request applies to multiple contract IDs, one change request form and attached program may be submitted which lists all applicable contract IDs.

The Part D Sponsor will receive an email correspondence regarding the approval of the MTMP change request.

The MTMP Change Request form can be found in Appendix 1.

30.8 – MTMP Reporting

The requirements stipulating that Part D Sponsors provide Medication Therapy Management Programs (MTMP) are described in Title I, Part 423, Subpart D, § 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 and participation in the MTMP will be submitted according to the following timeline (note: Period 2 encompasses one full year): Data related to the identification and participation 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 should be 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. 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 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 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 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 numeric field.
8. The number of beneficiaries who declined to participate in the MTMP during the specified time period above. 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. 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

$$\left[\begin{array}{l}\text{Total prescription cost} \\ \text{per MTMP beneficiary} \\ \text{per month}\end{array}\right] = \frac{\sum_{i}^{n}\left(\sum_{\text{j}}^{\text{m}}(\text{Gross Drug Cost}\right)}{\sum_{i}^{n}(\text{Member Months in Reporting Period})}$$

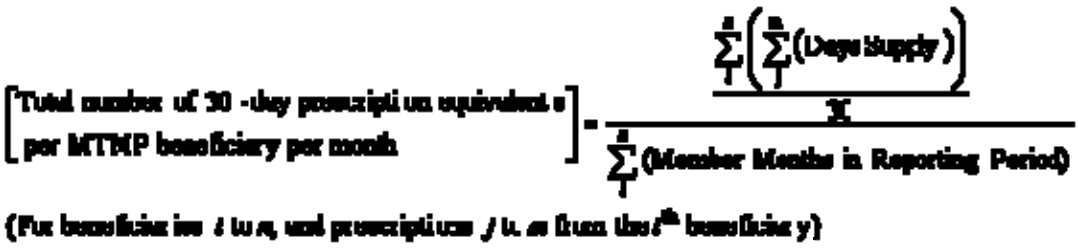
$\{\text{Gross Drug Cost} = (\text{Ingredient Cost Paid} + \text{Dispensing Fee} + \text{Sales Tax}).$

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:



These MTMP reporting requirements are included in the 2007 Medicare Part D Reporting Requirements, and will be available on the CMS website in January 2007. The 2006 Final Medicare Part D Reporting Requirements, dated April 18, 2005 and updated on January 26, 2006, 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 MA plan, as described in 42 CFR 422.4(a)(3), that offers qualified prescription drug coverage, is excepted from the requirement to establish a MTMP.

30.10 – Coordination with Care Management Plans

The Chronic Care Improvement Program, now 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.

During rulemaking we discussed that Part D plans should work with Medicare Health Support Organizations (MHSOs) and we codified this requirement in the final

regulations. Consequently, 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 that are enrolled in MHSOs in a manner specified by CMS. We will be issuing further guidance in the near future to facilitate this communication, since we acknowledge that MHSOs need this valuable data in order to provide the comprehensive care management that is intended under the MSHO program.

We note that in sharing the data, both the CCIP 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.

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 under §422.152(b) for MA plans by using the Consumer Assessment of Healthcare Providers and System (CAHPS) Survey.

The purpose of the 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. One major constraint is pilot testing of the survey cannot begin until early in 2006. CMS, AHRQ and the AHRQ CAHPS team are currently piloting the final survey instrument. We expect the initial consumer surveys will be implemented as part of the MA survey for MA plans. There will be a separate survey process for the stand-alone PDPs which will follow the traditional process for MA plans in 2007. Since the purpose of the survey is to help consumers choose among the plan options, during the development process we have tried to focus on things that may vary across plans versus satisfaction with the overall benefit. Although the plans are actuarially equivalent, there will be differences in formularies, customer service, informational materials, etc.

40.2 – Part D Plan Follow-up Responsibilities

Specific responsibilities for plan follow-up, once developed, will be described here.

50 – Electronic Prescription Program (E-prescribing)

50.1 – Terminology

For the purposes of this Manual section, 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, because the imposition of approved industry e-prescribing standards would likely impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists using such faxes, 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.

50.2 – General Rule

The currently promulgated e-prescribing regulations establish a framework from which a robust, interoperable e-prescribing environment can develop and grow. Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended Title XVIII of the Social Security Act (the Act) to establish the voluntary Prescription Drug Benefit Program. Section 101 of the 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. Section 42 C.F.R. 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 4010/4010A1 is the standard to be used for transmitting eligibility queries and responses between part D sponsors and prescribers. The NCPDP Telecom Version 5.1, and the analogous Batch Version 1.1, is the standard to be used for transmitting eligibility inquiries and responses between dispensers and part D sponsors. While plans are not typically involved directly in transmission of prescription information between prescribers and dispensers, plans are expected to support both entities in complying with the standards should those parties desire to transmit prescriptions electronically.

Prescribers and dispensers communicating a prescription or prescription-related information electronically for Medicare Part D eligible beneficiaries must also comply with the same "foundation standards", but communications between them is conducted through a different standard, i.e. the NCPDP SCRIPT standard, than that used to communicate with plans. 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 50.4. 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.

Since the "foundation standards" are merely the beginning, Part D plans will also be responsible for complying with future e-prescribing rules promulgated subsequent to the completion of the 2006 e-prescribing pilots mandated by the MMA and the required CMS report to Congress in 2007. We expect that these final standards will enhance the

capability of the e-prescribing process and improve quality of care for Part D eligible Medicare beneficiaries.

50.3 – State Law Preemptions

Section 1860D-4(e)(5) 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.

50.4 – Standards for E-Prescribing

The final rule published in the Federal Register on November, 7, 2005 adopted three foundation e-prescribing standards with which Part D Sponsors's 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 that there is adequate industry experience with these standards. However, we are including these standards in the pilot project to ensure their interoperability with various other standards. Pilot testing of these standards with regard to other electronic prescribing transactions will conclude on 12/31/06, after which time a report to Congress on the pilot results will be issued. These 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: CMS adopted NCPDP SCRIPT 5.0 as a foundation standard. Because of its additional functionality and features, CMS also allows for the voluntary use of NCPDP SCRIPT Standard 8.1 in place of NCPDP SCRIPT 5.0, but only for the communication of a prescription or prescription-related information between prescribers and dispensers for the functions listed above.

2. Eligibility standards.

- For transmitting eligibility inquires 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 inquires 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.

50.5 – 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 Part 162, or the NCPDP or ASC websites 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.

50.6 – 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

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 that further details plan requirements for following best practices in drug utilization management. This guidance is available on the CMS website at:

www.cms.hhs.gov/PrescriptionDrugCovContra/03_RXContracting_FormularyGuidance.asp#TopOfPage .

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 without limitation 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 not prior authorize or otherwise limit dispensing of formulary alternatives on the basis of prior usage of the OTC product.

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 administrative portion of the bid and, thus, ultimately reflected in premiums).

Plans choosing to include OTC products within their utilization management programs must understand and be prepared to appropriately educate their enrollees on the difference between OTCs provided as administrative costs as opposed to covered part D drugs. While beneficiaries will (and must) enjoy no direct cost-sharing on these OTCs,

they will also 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 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 MA plan, as described in 42 CFR 422.4(a)(3), that offers qualified prescription drug coverage, is excepted from the requirement to establish a drug utilization management program.

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 form 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 must 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)