DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

**CENTER FOR DRUG and HEALTH PLAN CHOICE**

TO: All Part D Plans

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Medicare Prescription Drug Benefit Manual – Chapter 7

DATE: September 18, 2008

CMS is pleased to release a revised version of Chapter 7 (Medication Therapy Management and Quality Improvement Program) of the Prescription Drug Benefit Manual for Contract Years 2008 and 2009. This revision incorporates policy changes and clarifications we have made in the 2008 and 2009 Call Letters, HPMS memoranda, and other guidance documents since the chapter's original issuance on May 5, 2007. Revisions are noted in red italics.

Chapter 7 contains information about Quality Assurance Requirements (i.e., Retrospective Drug Utilization Review, Medication Error Identification and Reduction); Medication Therapy Management Programs; Consumer Satisfaction Surveys; Electronic Prescription Program Requirements; Drug Utilization Management Programs; and Part D Complaints Processing.

If you have any questions regarding Chapter 7, please contact CDR Greg Dill at (312) 353-1754 or Gregory.Dill@cms.hhs.gov. Please note that the revised Chapter 7 will be posted on our Prescription Drug Benefit Manual web page at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage .

# CMS Manual System

## Pub. 100-18 Medicare Prescription Drug Benefit Manual

**Department of Health & Human Services (DHHS)**
**Centers for Medicare & Medicaid Services (CMS)**

**Transmittal 3** **Date: September 5, 2008**

**SUBJECT: Initial release of Chapter 7-Medication Therapy Management and Quality Improvement Program**

I. **SUMMARY OF CHANGES:** The initial publication of Chapter 7 of the Medicare Prescription Drug Benefit Manual includes information on Part D Quality Assurance Requirements, Medication Therapy Management, Consumer Satisfaction Surveys, Electronic Prescription Program Requirements, Drug Utilization Management, and Part D Complaints Processing.

**NEW/REVISED MATERIAL - EFFECTIVE DATE*: September 1, 2008**
**IMPLEMENTATION DATE: September 1, 2008**

***Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.***

**II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)**
**(R = REVISED, N = NEW, D = DELETED)**

| R/N/D | CHAPTER/SECTION/SUBSECTION/TITLE |
|---|---|
| N | 7/Entire Chapter |

**III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.**

**IV. ATTACHMENTS:**

| | |
|---|---|
| | **Business Requirements** |
| X | **Manual Instruction** |
| | **Confidential Requirements** |
| | **One-Time Notification** |
| | **Recurring Update Notification** |

***Unless otherwise specified, the effective date is the date of service.**

# Prescription Drug Benefit Manual

## Chapter 7 – Medication Therapy Management and Quality Improvement Program

---

**Table of Contents**

***(Rev.3, 09-05-08)***

# 10 – Medication Therapy Management and Quality Improvement Program

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

## 10.1 - Introduction

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

Title 42 CFR Part 423, Subpart D, establishes the requirements Part D *sponsors* 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

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

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.

*CMS maintains* 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 CFR. 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.

*Immediate need – means a complaint that is related to the beneficiary's need for medication when the beneficiary has 2 or less days of medication.*

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

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

## 20.1 – General Rule

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

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 Part D sponsor's comprehensive quality assurances system will ensure enrollees receive access to high quality prescription drug coverage. As a result, the Part D sponsor's* QA measures and systems *minimally* include:

1. Representation that the *Part D* sponsor requires network providers to comply with minimum standards for pharmacy practice as established by the States.

2. Concurrent drug utilization review *(DUR)* systems, policies and procedures.

3. Retrospective *DUR* 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 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 Act (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 *at the point-of-care*, thereby improving *overall* medication use. Therefore, CMS recommends Part D sponsors incorporate their electronic prescription drug program within their quality assurance system.

## 20.2 – Compliance With State Standards

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

*Part D sponsors are required in 42 CFR 423.153(c)(1) to ensure their existing quality assurance system includes representation that network providers comply with minimum standards for pharmacy practice.* While CMS believes that current pharmacy practice standards established by the States provide applicable minimum standards for all pharmacy practice settings, CMS encourages sponsors and network pharmacies to establish and agree upon additional quality assurance standards as necessary.

## 20.3 – *Concurrent Drug Utilization Review (DUR)*

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

A Part D sponsor must have concurrent DUR 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 Part D sponsor's concurrent DUR program* must include, but *is* not limited to, the following *checks each time a prescription is dispensed:*

- 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

## 20.4 – *Retrospective Drug Utilization Review (RDUR)*

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

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.

*It is vitally important,* upon notification or discovery of an allegation of fraud, abuse or suspected pattern of inappropriate drug utilization, the Part D sponsor reviews 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.

## 20.5 – *Medication Error Identification and Reduction (MEIR)*

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

While *CMS* currently does not require external medication error reporting, *CMS* does require *sponsors* to implement internal *MEIR* systems as described in 42 CFR 423.153(c)(4). *CMS* also requires *sponsors* to provide 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 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. *CMS* expects plans to consider their internal control systems, current monitoring program and, ultimately, what is in the best interest of their *enrollees*, 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 12501 (March 14, 2003)).

## 20.6 – *Medwatch Reporting*

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

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 *(including OTCs and dietary supplements)*. 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. *Healthcare professionals and consumers may report adverse events and product problems to MedWatch by calling 1800-FDA-1088, by submitting the MedWatch 3500 form by mail or fax, or by going online to the FDA Web page. CMS encourages Part D sponsors* 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 FDA *MedWatch* Web page *(see Appendix A).*

## 20.7 – *CMS Performance Measures*

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

*CMS* believes that utilization of *specific performance* measures help ensure *Medicare* beneficiaries receive the highest quality prescription drug coverage and services. *Publicly available measures encourage Part D sponsors to improve the quality of services and to maximize their ratings in an effort to attract new enrollees through the competitive nature of the Part D program. To facilitate this process, CMS continuously reviews various data sources to refine and identify new performance measures. CMS generally relies upon data received from internal CMS systems, the complaints tracking module (CTM), the Medicare Prescription Drug Plan Finder Tool, Appeals Data, and Call Center statistics. As well, CMS also integrates information into the measures from the Medicare Part D Reporting Requirements (see Appendix A).*

*After a comprehensive analysis of these various data streams, CMS has identified several key Part D performance areas CMS believes are* the basis for evaluating prescription drug coverage *across the Part D program. Some of these areas* include customer service, complaints, appeals, data systems, *satisfaction, and* drug pricing. While these *measures* are broad, elements of each *can be integrated together to ensure* beneficiaries receive superior services. For instance, independent review entity (IRE) data *is* used in conjunction with information from 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. *Star ratings are assigned and displayed on plan finder. While CMS investigates and audits those plans with lower than average ratings, beneficiaries will likely migrate to those plans with the highest ratings and highest quality prescription drug coverage.*

*The development of performance measures is a particularly dynamic process based upon the availability of new information. As continuing analyses are completed and show promise in improving the quality of drug coverage, additional measures will be added to the existing inventory of measures.*

*CMS provides preview periods for Part D sponsors' review of individual contract data and ratings as part of the performance measures. Sponsors are required to review and notify CMS of any data inaccuracies during these periods, as well as submit any questions or issues identified by the sponsors' preview.*

Finally, CMS is 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.

## *20.8 – Information for Quality Improvement Organizations (QIOs)*

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

*CMS* expects that the QIOs will work with providers, practitioners, and *Part D sponsors* 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, *CMS* expects that *Part D sponsors*, 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 *Part D quality of care* 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)

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

## 30.1 – General Rule

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

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.

*Since the outset of the Medicare Prescription Drug Benefit, the MTMP requirements have provided a framework that gives Part D sponsors maximum flexibility to develop MTMPs. In exchange for this flexibility, CMS expects Part D sponsors to analyze and evaluate their MTMPs and make changes to continuously improve their programs.*

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. *CMS is continuing to monitor and evaluate MTMPs offered by Part D sponsors in an effort to identify and understand attributes of MTMPs that may be most effective for the Medicare program.* 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.

*The MTMP Web site (see Appendix 1) contains more information related to Part D MTMP reporting requirements.*

## 30.2 – Targeted Beneficiaries

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

Targeted beneficiaries for the MTMP as described in 42 CFR 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 *Medicare Modernization Act* (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 *sponsors* 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, *CMS* envisions 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. *CMS* expects 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 *establishes the cost thresholds for the* level of annual costs beneficiaries are likely to have incurred to be eligible for participation in MTMPs as targeted beneficiaries. *This predetermined level will be designated in the annual call letter and in the annual MTMP submission memo to Part D sponsors.*

*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. Should an enrollee desire to permanently opt-out of the plan's MTM program, the plan must honor the request and not re-target the beneficiary in future contract years; however, if the enrollee actively seeks enrollment into the MTMP at a later time, perhaps due to a level of care change, the plan must allow the enrollee to participate as long as they meet the necessary MTMP requirements.*

Although participation in MTMPs is voluntary for beneficiaries, *CMS* hopes 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

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

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

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

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. Part D sponsors 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, 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

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

Each Part D sponsor is required to incorporate an MTMP into its plans' benefit structure. Annually, all Part D sponsors, including renewing sponsors and new applicants, must submit an 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 *submitted* through the Health Plan Management System (HPMS) in the MTMP module. *This interface was established to enable Part D sponsors to enter, edit, and submit their MTMP descriptions within HPMS at the contract level. The submitted* MTMP descriptions should be as detailed as possible *and an MTMP submission template is provided as a guide to facilitate the submission process. This memorandum is updated annually and posted on the MTMP Web page (see Appendix A).*

CMS will communicate *with each sponsor* regarding the status of *their MTMP review (*including *if* the MTMP requires resubmission to correct deficiencies or if the MTMP meets all of the minimum requirements *for the contract year). Communications will be sent via email to the HPMS MTMP Main Contact and Medicare Compliance Officer. Sponsors should ensure that their contact information is up-to-date in HMPS under the Contract Management section.*

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 that *sponsors are* required to submit as part of their MTMP applications.

**Information that MUST be included with the MTMP Application**

- Criteria #1: Multiple Chronic Diseases
    - Provide the minimum number of chronic diseases a beneficiary must have to meet this criterion. (**NOTE:** the definition of multiple is any *number* 2 or more)
    - Provide the *specific* name of each chronic disease that applies *or if any chronic disease 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 *minimum* number of covered Part D drugs that a beneficiary must have filled to meet this criterion. (**NOTE**: the definition of multiple is any *number* 2 or more)
    - Provide the type of covered Part D drugs that applies (i.e. *any Part D drug,* chronic/ *maintenance drugs,* disease-specific, *specific Part D drug classes*).
    - Example: A beneficiary must have filled any 5 or more distinct covered Part D drugs.
- Criteria #3: *Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary.*

- Provide a detailed description of the analytical procedure used to determine if a beneficiary is likely to incur annual costs *in excess of a predetermined level as specified by the Secretary for all covered Part D drugs.*

- Example 1: *Provide the* monthly or quarterly dollar threshold per beneficiary for covered Part D drugs *(the specific threshold should be provided).*

- Example 2: *Describe the* 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

- *Resources and* 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 *Pharmacy Benefits Manager* (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

## 30.6 – MTMP Approval Considerations

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

During the MTMP approval process, *CMS* reviews the MTMP submission to ensure *Part D sponsors* 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 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 *CMS'* 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.

## 30.7 – Mid–Year MTMP Changes

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

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 MTMP changes must be submitted to CMS for review and approval prior to the implementation of requested changes.

*CMS has* a four 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. 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 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 made *using the MTMP change request form. At the time of the change request, the revised MTMP description should be submitted operationally through HPMS.* Part D sponsors will receive an email correspondence regarding the approval of the MTMP change request. Part D plans must not implement 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 *made*

*using the MTMP change request form. At the time of the change request, the revised MTMP description should be submitted operationally through HPMS.* The Part D sponsor will receive an email correspondence regarding the approval of the MTMP change request.

*A memo containing information and additional instruction related to Part D MTMP change requests is posted at MTMP Web page, see Appendix A.*

## 30.8 – MTMP Reporting

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

*Part D sponsors will be required to provide CMS with data on a semiannual basis that will allow CMS to determine whether plan MTMPs comply with the standards outlined in this chapter. For more information about these reporting requirements, see Appendix A for the MTMP Web page.*

## *30.9 – Claims Processing for MTM Services*

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

*For MTM claims processing, covered entities should use the American Standards Committee (ASC) X12 837P Version 4010/4010A1. CMS articulated in our January 28, 2005 Final Rule on the Medicare Prescription Drug Benefit that CMS viewed MTM as a clinical service (70 FR 4194, 4231). Therefore, claims for MTM would be considered professional health care claims rather than retail pharmacy drug claims. Pursuant to the Health Insurance Portability and Accountability Act (HIPAA) of 1996, the ASC X12 837P was adopted as the transaction standard for professional health care claims. Therefore, similar to physician clinical services, if MTM providers bill Part D sponsors electronically for MTM services, such billing claims must be transmitted using the ASC X12 837 P Version 4010/4010A1. Part D sponsors are not precluded from using the NCPDP 5.1 system edits as a method to identify targeted beneficiaries, or provide applicable information at the point of service to pharmacists or other MTM providers responsible for providing the MTM services, but the health care claim must be transmitted using the ASC X12 837P.*

*While CMS adheres to its foregoing interpretation of the regulations requiring that MTM retail pharmacy services be reported using the X12 837P standard, CMS recognizes that a reasonable argument could be advanced in response to the Department of Health and Human Services (HHS) seeking to enforce this regulation, contending that the regulations could be read to instead direct the use of the NCPDP, Version 5.1 standard for such services. CMS further realizes that notice and comment rulemaking, which HHS anticipates initiating in the near future, will very likely resolve the apparent ambiguity of these regulatory provisions. In light of the foregoing planned rulemaking and the uncertain outcome of any enforcement action, CMS elects not to take enforcement action against those covered entities that continue to use the NCPDP, Version 5.1 standard for this transaction.*

## 40 – Consumer Satisfaction Surveys

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

## 40.1 – General Rule

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

Section 1860D-4(d) of the Act specifies that *consumer satisfaction* surveys be conducted *for Part D* in a manner similar to how they are conducted for MA plans. Accordingly, *CMS* will use the Consumer Assessment of Healthcare Providers and System (CAHPS®) Survey process established for Part C at 42 CFR 422.152(b).

*The CAHPS® survey is conducted annually to assess the experiences of beneficiaries with the services they receive from their health plan. The CAHPS® survey is designed to provide information in a timely manner to Medicare beneficiaries in order to facilitate their plan choice which is normally made during the fall of the year. The survey is also used by CMS and MA organizations as a tool in assessing and benchmarking plan performance. Survey respondents are comprised of a randomly selected sample of plan enrollees who were members of a plan for at least 6 months.*

*The Medicare CAHPS® survey includes questions about prescription drug benefits in order to assess Medicare beneficiaries' experiences with Medicare prescription drug coverage. For Medicare Advantage plans, the questions relevant to Part D are asked only of those Medicare Advantage enrollees with prescription drug coverage, whereas stand-alone Part D plan enrollees are sent a separate survey. CAHPS® questions focus on beneficiaries' experience with getting needed information about their prescription drug plan and with getting the prescription drugs they need.*

*The results of the Medicare CAHPS® survey are compiled annually and disseminated to all Part D sponsors in January of each year. For purposes of display on the Medicare Prescription Drug Plan Finder, elements of the CAHPS® survey are compared to a national average and assigned star ratings depending on their item or composite average. During annual enrollment, beneficiaries can review the star ratings as part of their overall decision making process about drug coverage for the upcoming contract year.*

## 40.2 – Part D Sponsor Follow-up Responsibilities

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

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

# 50 – Electronic Prescription Program (E-prescribing)

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

## 50.1 – General Rule

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

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.

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.

*To satisfy these requirements, CMS expects Part D sponsors to have all the necessary contracts and systems in place should prescribers desire to electronically transmit prescriptions for their Medicare eligible patients. This includes ensuring that network pharmacies can receive electronic prescriptions (with allowance for exceptions when it is impractical or otherwise could jeopardize beneficiary access) in accordance with the adopted standards.*

*In order to monitor the uptake of electronic prescribing in the Part D program, CMS needs to collect prescription level data that demonstrates the frequency of electronic prescribing. CMS believes the most effective method for gathering this data is use of the Prescription Origin Code via the NCPDP 5.1 optional field 419 DJ. CMS expects to add a new optional field to the Prescription Drug Event (PDE) record that will capture the Prescription Origin Code, and CMS strongly recommends that Part D sponsors work with their network pharmacies to voluntarily begin using the 419 DJ field.*

Part D plans will also be responsible for complying with future e-prescribing standards *that are adopted as part of the industry standard or regulatory process. 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. CMS expects significant activity in this area given the rapid development of e-prescribing and its ability to improve quality of care for Part D eligible Medicare beneficiaries. Part D sponsors should familiarize themselves with the CMS e-prescribing Web site (see Appendix A) and remain current with all the e-prescribing requirements, standards and exemptions.*

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. HHS 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

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

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 eligible individuals. CMS has 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

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

The e-prescribing and the prescription drug program final rule published in the Federal Register on November 7, 2005, (70 FR 67568) adopted foundation e-prescribing standards with which Part D sponsors' e-prescribing programs must comply. *CMS* refers to them as "foundation standards" because they provided *an initial* foundation for e-prescribing implementation. The Foundation Standards are as follows:

1. Prescription standards.

   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.

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.

*The MMA also required CMS to develop "initial uniform standards" for e-prescribing and pilot test these standards for purposes of furthering e-prescribing. On April 7, 2008, CMS issued an e-prescribing and prescription drug program final rule (73 FR 18918) adopting additional e-prescribing standards with which Part D sponsors' e-prescribing programs must also comply. These initial standards are:*

3. *Medication History*

   - *To provide for the communication of Part D medication history information among Medicare Part D sponsors, prescribers, and dispensers—*

     *The National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1 (Version 8.1).*

4. *Formulary and Benefits*

   - *For transmitting formulary and benefits information between prescribers and Part D sponsors—*

     *The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0), October 2005.*

5. *Provider Identifier*

- *To identify an individual health care provider to Part D sponsors, prescribers and dispensers, in electronically transmitted prescriptions or prescription-related materials for Part D covered drugs for Part D eligible individuals—*

  *The National Provider Identifier (NPI), as defined at 45 CFR 162.406.*

## 50.4 – Exemptions

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

*The November 7, 2005, foundation standards final rule (70 FR 67568) implemented specific exemptions for certain entities potentially involved in e-prescribing. These exemptions continue to change as improvements are realized in the e-prescribing environment. Part D sponsors should remain aware of these exemptions and work with their network pharmacies as necessary.*

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. 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.

4. 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.

## 50.5 – Promotion of Electronic Prescribing by MA-PD Plans

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

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

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

## 60.1 – General Rule

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

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. *Part D sponsors will be required to submit their utilization management tools to CMS for approval as a component of the sponsor's formulary. Further information on formulary benefit management tools, including CMS expectations on criteria, can be found in Chapter 6 of the Medicare Prescription Drug Benefit Manual.*

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

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

*Over-the-counter* drugs (OTCs), many of which (e.g., Prilosec OTC® and Zyrtec®) were available by prescription when first marketed, may offer significantly *less expensive* alternatives to branded prescription medications. The Medicare Modernization Act (MMA) does not allow Medicare plans to include OTCs as part of their drug benefit or supplemental coverage. However CMS allows *Part D* sponsors the option to provide *OTCs* as part of their administrative cost structure. *Consequently, for those Part D sponsors who elect to do so, OTCs are a component of the plan premium and result in OTCs provided to the enrollee without any direct cost-sharing at the point of sale. Furthermore, if Part D sponsors elect to provide OTCs they*

*must do so for the full duration of the contract year and cannot limit OTCs to certain benefit phases.*

*Part D sponsors may offer OTCs either as (1) part of general drug utilization management or (2) as part of a step therapy protocol. To ensure safe and effective use of OTCs, Part D sponsors will submit an OTC drug file, along with their HPMS formulary submission, identifying which OTCs will be provided. Upon bid approval, Part D sponsors are prohibited from removing OTCs from their plan offering for the full contract year. Enhancements of OTC offerings (i.e., additional OTC step 1 drugs or providing recently converted OTCs as part of general drug utilization management) are permitted mid-year.*

*If a Part D sponsor includes OTCs as a part of its utilization management strategy, the sponsor* 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. *Conversely, if OTCs are offered as part of an approved step therapy protocol, the step therapy edit is not required to be resolvable at point of sale; however, Part D sponsors must be able to disclose the protocol requirements to beneficiaries or their representatives in accordance with section 60.4 of this chapter.*

*Part D sponsors* choosing to include OTC products should 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 enjoy no direct cost-sharing on these OTCs, they will not have the same beneficiary protections*, such as coverage determinations or temporary fills,* required to ensure appropriate access to Part D drugs. (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.)

## *60.3 – Exception for Private Fee-for-Service MA Plans*
***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

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 the requirements contained in this chapter.

## *60.4 – Drug Utilization Management Disclosure Requirements*
***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

*Part D sponsors must provide current and prospective enrollees (or their physician or authorized representative) with information regarding specific prior authorization criteria and other utilization management requirements. This information must be made available on a timely basis so that beneficiaries can make informed enrollment decisions and so that physicians*

*can access information that will help avoid delays at the pharmacy and potential interruptions in drug therapy.*

*42 CFR 423.128(c)(1)(v) and (c)(2) require Part D sponsors to provide Part D eligible beneficiaries information about their formulary and utilization management procedures. Similarly, 42 CFR 423.128(d) requires Part D sponsors to provide current and prospective beneficiaries "specific information" such as specific prior authorization requirements, "on a timely basis" through a toll-free customer service call center. Accordingly, Part D sponsors must explain their utilization management requirements and criteria through their customer service call centers. To ensure that such requests are addressed in a timely manner, if the customer service representative is unable to adequately address or answer the enrollee's (or his/her authorized representative's) or physician's questions, sponsors must expedite the call to their pharmacy technical help call center where further detail can be provided on the drug and utilization management criteria in question.*

## *60.5 – Posting of Prior Authorization (PA) Requirements*

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

*Part D sponsors must post their approved PA criteria on plan Web sites (including PA criteria applied to supplementary drugs provided by enhanced alternative plans). Given the uniformity that results from utilization of a standardized HPMS submission form during formulary review, CMS believes that Web page posting of this information will augment the Part D sponsor's ability to rapidly provide this information, improve transparency and allow Part D plan comparison during enrollment. Part D sponsors will need to ensure that approved PA criteria are posted on Part D sponsor Web sites in the formulary section by November 15 each year. CMS expects Part D sponsors to make these criteria available for beneficiary viewing either from a link when the drug identified with PA is displayed or from a general link on the formulary page. Part D sponsors will be expected to display all of the PA criteria content contained within the CMS approved HPMS-PA file without modification. Minor grammatical changes will be permitted for display purposes in cases where abbreviations or grammatical errors occurred due to HPMS PA file character limitations.*

## *60.6 – Revision of Utilization Management Criteria Requirements*

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

*Part D sponsors must not change existing utilization management criteria (i.e., prior authorization, step therapy, or quantity limits) to make them more restrictive or limiting without direct CMS approval. During the contract year, a Part D sponsor should not need significant revision of its approved criteria. For instance, submitted PA criteria should already have been evaluated for clinical accuracy, since in accordance with 42 CFR 423.120(b)(vi), the sponsor's Pharmacy and Therapeutics Committee has completed a thorough review of proposed PA criteria prior to submission of the formulary to CMS. Furthermore, during the annual enrollment period, beneficiaries may view plan prior authorization criteria as a component of making informed decisions. To permit changes after the annual enrollment period could undermine beneficiaries' enrollment decisions and anticipated drug coverage. As a result, it is CMS' expectation that Part D sponsors will not update their utilization management criteria*

*except under extraordinary circumstances, such as when new drug safety-related information becomes available during the contract year (e.g., FDA release of a new Black Box warning).*

*In the event that a Part D sponsor needs to make its utilization management criteria more restrictive, the sponsor will be required to submit the proposed changes to CMS in advance. CMS will address each request in order of receipt and will generally only permit criteria changes to incorporate new safety information. Conversely, Part D sponsors are not required to receive CMS approval in order to make their existing utilization management criteria less restrictive. For example, when sponsors are modifying their criteria to indicate coverage for new medically-accepted indications or removing certain diagnostic criteria, the sponsors are not required to notify CMS of such mid-year changes. However, even though there is no notice requirement, sponsors must still submit the appropriate updated utilization management criteria document reflecting the formulary enhancements during the next available HPMS formulary upload window.*

## *70 - Part D Complaints Processing*

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

## *70.1 – General Rule*

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

*In accordance with 42 CFR 423.564, Part D sponsors must provide meaningful procedures for timely hearing and resolving enrollee grievances. Chapter 18 of the Medicare Prescription Drug Benefit Manual (see Appendix A for Web site) defines a grievance as any complaint or dispute which the plan directly receives, other than one that involves a coverage determination or a low-income subsidy or late enrollment penalty determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D sponsor, regardless of whether remedial action is requested. A grievance may also include a complaint that a Part D plan sponsor refused to expedite a coverage determination or redetermination. Grievances may include complaints regarding the timeliness, appropriateness, access to, and/or setting of a provided item. CMS recommends that plans record and monitor grievances separately from Complaints Tracking Module (CTM) complaints. Upon receiving a complaint, a Part D sponsor must promptly review the submitted case and notify the enrollee of its decision as expeditiously as the case requires based upon the enrollee's health status. To facilitate and streamline this process CMS has developed the CTM system for tracking and processing complaints received from beneficiaries and providers specifically related to the Part D Medicare Prescription Drug Program. CTM may be populated by a number of sources, including CMS contractor at 1800Medicare, CMS staff or Part D sponsors. Given the time sensitive nature of many of the submitted complaints, Part D sponsors should continuously access, view, respond and resolve the Part D complaints(s) submitted to their organization in CTM.*

*Additionally, CMS recognizes that Part D sponsors are the primary resource Medicare beneficiaries rely upon for the prompt resolution of their inquiries. CMS expects each Part D sponsor to educate their members to ensure that beneficiaries call the sponsor's call center directly with any Part D related complaints.*

## *70.2 – Timeframes for Complaints Processing*

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

*All Part D sponsors are accountable for the prompt resolution of CMS recorded complaints in the CTM. As a result, Part D sponsors will resolve any complaints designated as "immediate need" (see Section 10.2 Definition of Terms) within 2 calendar days of receipt into CTM.*

*Part D Sponsors are required to have at least 95% of cases designated as "immediate need" resolved within 2 calendar days of receipt. For a given month, CMS will calculate the proportion of "immediate need" complaints that remain unresolved at the end of each month. The analysis will exclude those complaints that can be identified as not attributable to the sponsor, such as SSA premium withhold, retroactive disenrollment, enrollment exception, and facilitated enrollment complaints.*

*Should a Part D sponsor not meet the 95% threshold, CMS will consider those organizations out of compliance with one or more Part D requirements, including but not limited to requirements related to enrollment; coverage determinations, appeals, and formulary exceptions; and claims processing. In that instance, CMS may conduct a targeted audit of the Part D sponsor. Where audit findings indicate that the sponsor is not meeting Part D requirements, CMS may demand the sponsor develop and complete a formal corrective action plan to rectify the deficiencies indicated by the audit. If there is significant non-compliance, CMS may impose intermediate sanctions (i.e., suspend marketing and enrollment activities or withhold CMS payments). If the non-compliance presents potential harm to beneficiaries, CMS may also pursue civil monetary penalties against the organization.*

## *Appendix A – Chapter 7 Related Web Sites*

***(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)***

*CMS e-prescribing Web site*

*www.cms.hhs.gov/eprescribing*

*CMS Medication Therapy Management Program Web site*

*http://www.cms.hhs.gov/PrescriptionDrugCovContra/082_MTM.asp#TopOfPage*

*CMS Reporting Requirements Web site*

*http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp*

*FDA Medwatch Reporting*

*http://www.fda.gov/medwatch*