

Prescription Drug Benefit Manual

Chapter 7 – Medication Therapy Management and Quality Improvement Program

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(Rev. 11, 02-19-10)

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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. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

For the purposes of this *chapter* 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.

[NOTE: Computer-generated fax transmissions start with data that is in an electronic form, and thus qualify as transmissions using electronic media. Absent the current exemption in 42 CFR 423.160(a)(3) to a particular Part D standard (the “NCPDP SCRIPT 8.1” standard), such transmissions could not meet the Part D e-prescribing standards (because they cannot be transmitted using NCPDP SCRIPT 8.1). The exemption was allowed due to fears that the imposition of final e-prescribing standards would drive computer-generated faxers to revert to paper.]

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 – *For Part D complaints, an “immediate” complaint is defined as a life-threatening complaint* that is related to the beneficiary’s need for medication when the beneficiary has 2 or less days of medication *remaining*.

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.

Urgent need – For Part D complaints, an “urgent” complaint is defined as a complaint that is related to the beneficiary’s need for medication when the beneficiary has 3 to 14 days of medication remaining.

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. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

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

Part D sponsors should maintain written concurrent DUR policies and procedures that explain the level of the DUR checks (i.e., whether they are imposed at the pharmacy and/or plan level), systems logic for establishing the edits, thresholds used to trigger the edits, and accompanying pharmacy messaging. These policies should detail how the aforementioned elements were established (e.g., thresholds used are based upon relevant clinical and drug information references), validated and revised. Sponsors' DUR policies should also address pharmacy requested overrides and detail how pharmacy override requests are evaluated and approved. Moreover, sponsors' policies should explain how trends in override requests (both approved and unapproved) are monitored and considered in ongoing formulary management.

Part D sponsors should be able to demonstrate how information obtained from their DUR program is used in their overall quality assurance system and improves their enrollees' quality of care.

20.4 – Retrospective Drug Utilization Review (RDUR)

(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

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.

Part D sponsors should maintain a written retrospective DUR policy that establishes clear objectives and identifies the relevant claims data proposed for review, the evaluation period, the criteria used in the evaluation, and the proposed interventions. The policy should also include a periodic assessment that determines the success of the proposed objectives, interventions, findings, and outcomes.

Part D sponsors should be innovative in improving the quality of care provided to enrollees through application of DUR. For example, Part D sponsors may want to apply retrospective DUR upon FDA issuance of a new drug safety warning to ensure enrollees and/or physicians are aware of alternative therapies. Alternatively, Part D sponsors may consider application of retrospective DUR for purposes of ensuring appropriate Part B versus Part D payment by working to obtain additional information after point-of-sale adjudication.

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. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

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).

The Part D sponsor's internal MEIR process should be fully documented and identify what types of medication errors will be collected internally. For example, Part D sponsors may receive calls or letters from enrollees containing a broad range of issues, including medication errors. Other operational functions may also receive and report medication errors, such as the sponsor's exceptions and appeals group, the clinical division involved in processing prior authorization forms, or the electronic prescribing group involved in resolving issues with the implementation of new e-prescribing standards. As a result, appropriate sponsor staff should be trained to identify potential reportable medication errors and understand how to evaluate resolve, document, and, if necessary, report to the appropriate authority (i.e., FDA, DEA).

As a component of the sponsor's error reduction program, a periodic evaluation of the medication errors should be completed looking for trends and patterns that require the sponsor's attention and resolution. Additionally, when appropriate, reported medication errors should be shared and discussed with downstream contractors to ensure that corrective actions are implemented and future errors are prevented.

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. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

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, *member* 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 *are* 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. *Plans with sustained low performance may be subject to compliance actions.*

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 *incorporated* to the existing inventory of measures.

In addition to the plan ratings displayed on plan finder, CMS will post information on operational and clinical measures on the CMS Web site <http://www.cms.hhs.gov>. These data include selected measures that are not ready for Medicare Options Compare (MOC) or the Medicare Prescription Drug Plan Finder (MPDPF), that are in development, are duplicative, or are limited by a small sample size. In contrast to the Plan Ratings available on the MOC or MPDPF on <http://www.medicare.gov>, information about sponsors' performance on these measures are displayed without any assignment of star ratings.

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. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

A Part D sponsor must have established an 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.

Until 2009, CMS did not identify specific medication therapy management (MTM) requirements beyond those contained in the Social Security Act. In large part this was due to the fact there was insufficient industry experience and no widely accepted standard practices for MTMPs. However, given the experience garnered from the first few years of the Part D program, CMS determined it necessary to provide more specific Part D MTMP instructions for enrollment methods, targeting procedures, and MTM services. In the 2010 Call Letter, CMS included policy guidance regarding the implementation of MTMPs. This policy guidance reflects common practices among Part D MTMPs that were derived from CMS' extensive review of MTMP applications, plan-reported data, exploratory research on MTM, informal interviews with Part D sponsors, and other relevant literature and data.

Sponsors are expected to analyze and evaluate their MTM programs and make changes to continuously improve their programs.

MTMP requirements do not apply to MA Private Fee for Service (MA-PFFS) organizations. However, considering MA-PFFS organizations have an equal responsibility to provide quality Part D products, CMS encourages MA-PFFS organizations to establish an MTM program to improve the quality of care furnished to Medicare beneficiaries.

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

30.2 – Targeted Beneficiaries

(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

Part D sponsors are expected to target beneficiaries who:

1. Have multiple chronic diseases;

- *In defining multiple chronic diseases, sponsors cannot require more than three chronic diseases as the minimum number of multiple chronic diseases and sponsors must target at least four of the following seven core chronic conditions:*
 1. *Hypertension;*
 2. *Heart Failure;*
 3. *Diabetes;*
 4. *Dyslipidemia;*
 5. *Respiratory Disease (such as asthma, chronic obstructive pulmonary disease (COPD), or chronic lung disorders;*
 6. *Bone Disease-arthritis (such as osteoporosis, osteoarthritis, or rheumatoid arthritis);*
 7. *Mental Health (such as depression, schizophrenia, bipolar disorder, or chronic and disabling disorders).*

2. Are taking multiple Part D drugs; and

- *In defining multiple Part D drugs, sponsors cannot require more than 8 Part D drugs as the minimum number of multiple covered Part D drugs. Sponsors may set this minimum threshold at any number equal to or between two and eight.*

3. Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary.

- *For CY 2010 the cost threshold will be \$3000, and sponsors' targeting criteria should be adjusted accordingly.*

Sponsors are required to target beneficiaries for enrollment at least quarterly during the year to allow more Medicare beneficiaries to have access to the MTM program earlier in the year. For example, daily, weekly, monthly, or quarterly targeting frequencies would meet this requirement. However, CMS also expects Part D sponsors to promote continuity of care by performing an end-of-year analysis that identifies current MTM program participants who will continue to meet the eligibility criteria for the next program year for the same plan. This targeting could be done to auto-enroll eligible beneficiaries in the plan's MTM program early in the next program year in order to provide MTM interventions with less interruption.

Additionally, sponsors are required to enroll targeted beneficiaries into MTM programs using only an opt-out method. A beneficiary that meets the targeting criteria would be auto-enrolled and considered to be enrolled unless he/she declines enrollment. The enrolled beneficiaries may refuse or decline individual services without having to disenroll from the program. This requirement will allow Medicare beneficiaries to have more access to MTM services and increase member compliance and enrollment into these programs. Part D sponsors are reminded that if an enrollee chooses to opt-out of the plan's MTM program, they must continue to apply their existing drug utilization management program to ensure the beneficiary receives high quality prescription drug coverage.

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 *sponsors* and pharmacists will coordinate these edits as part of the terms and conditions of their contracts. *Therefore, Part D sponsors* need to develop appropriate mechanisms for identifying and notifying targeted beneficiaries who are eligible for MTMP services.

Should an enrollee desire to permanently opt-out of the plan's MTM program, the plan *should* 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 *he or she* 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 – MTM services

(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

At a minimum, Part D sponsors are expected to offer MTM services that include the following:

- 1. Offer a comprehensive medication review (CMR) by a pharmacist or other qualified provider at least annually to all targeted beneficiaries enrolled in the MTM program. A CMR is a review of a beneficiary's medications, including prescription, over-the-counter (OTC) medications, herbal therapies and dietary supplements, that is intended to aid in assessing medication therapy and optimizing patient outcomes. While initial preparations to assess medication use and identify medication-related problems before the patient interaction may be conducted 'behind the scenes', they are only a piece of the overall comprehensive medication review. CMS recognizes the importance of offering an interactive, person-to-person consultation with the beneficiary for a complete assessment of the beneficiary's needs to improve medication use or outcomes. This includes three components:*

- a. *Review of medications to assess medication use and identify medication-related problems. This may be conducted person-to-person or ‘behind the scenes’ by a qualified provider and/or using computerized, clinical algorithms.*
 - b. *Offering to provide to each targeted beneficiary enrolled in the MTM program an interactive, person-to-person consultation performed by a qualified provider. This real-time interaction may be face-to-face or through other interactive methods such as the telephone. This interaction may include further assessment of the beneficiary’s medication history and use (could enable sponsors to collect information from the beneficiary, such as OTC medications or supplements, that is outside of the claims data they have access to), health status, clinical information, adverse events, or other issues that could affect medication use or outcomes.*
 - c. *Implementation of a systematic process to summarize the interactive consultation and provide an individualized written “take-away” to the beneficiary such as a personal medication record, reconciled medication list, action plan, recommendations for monitoring, education, or self-management, etc.*
2. *For ongoing monitoring, perform targeted medication reviews for all beneficiaries enrolled in the MTM program, no less often than quarterly, to assess medication use since the CMR, monitor whether any unresolved issues need attention, new drug therapy problems have arisen, or if the beneficiary has experienced a transition in care. Part D sponsors must assess the findings of these reviews to determine if a follow-up intervention is necessary and if the intervention is warranted for the beneficiary and/or prescriber. These assessments could be person-to-person and/or system generated. The follow-up interventions should be interactive, if possible, but may be delivered via U.S. mail or other means.*
3. *Offer interventions targeted to prescribers to resolve medication-related problems or other opportunities to optimize the targeted beneficiary’s medication use. These interactions may be passive (e.g., faxed, mailed) or interactive when determined necessary.*

For targeted beneficiaries enrolled in the MTM program that are in an LTC setting, sponsors are not required to offer the interactive CMR component, but still must perform quarterly medication reviews and offer interventions targeted to the beneficiaries’ prescribers.

While all targeted beneficiaries should be offered a CMR, the beneficiaries may refuse the CMR or individual services. Even if a beneficiary declines the CMR, sponsors should conduct quarterly targeted medication reviews for all targeted beneficiaries and offer interventions to the prescriber.

CMS expects that sponsors will have procedures in place to drive participation and follow-up with beneficiaries that do not respond to initial offers for MTM services. In addition, sponsors

are expected to consider using more than one approach when possible to reach all eligible patients who may wish to receive MTM services.

30.4 – *Use of Experts*

(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

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.

30.5 – *Considerations in MTMP Fees*

(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

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.

30.6 – *MTMP Application*

(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

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. *[NOTE: MTMPs offered by MA-PFFS organizations **should** meet the same standards as other Part D MTMPs.]*

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 HPMS 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 *of* two or more)
 - Provide the specific name of each chronic disease that applies or if any chronic disease applies.
 - Example *1:* A beneficiary must have *any two or more* chronic diseases.
 - *Example 2: A beneficiary must have two or more chronic diseases. The following chronic diseases will be targeted: Respiratory Disease-asthma, Respiratory Disease-COPD, Bone Disease-arthritis-rheumatoid arthritis, dyslipidemia, Mental Health-depression, autoimmune disorders, HIV/AIDS.*
- 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 of two 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 1: A beneficiary must have filled any five or more distinct covered Part D drugs.
- Example 2: A beneficiary must have filled any two or more distinct covered Part D chronic/maintenance 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
 - *Provide the frequency of identifying beneficiaries which is required to be no less frequently than quarterly. For example, daily, weekly, monthly or quarterly targeting frequencies should meet this requirement.*
 - *Describe the data evaluated for targeting eligible beneficiaries. Examples include drug claims, medical claims, lab data, etc.*
- Methods of enrollment and disenrollment. *Sponsors are required to enroll targeted beneficiaries using an opt-out model.*
- Type, frequency and recipient of interventions.
 - *Provide the recipient of MTM interventions. This will automatically default to beneficiary and prescriber. Other recipients may also be provided.*
 - *Provide the specific beneficiary interventions;*
 - *This will automatically default to review of medications, interactive, person-to-person consultation, and individualized, written summary of the interactive consultation.*
 - *Selections must be provided for the delivery method(s) for the interactive consultation and the type(s) of written takeaways.*

- *Targeted medication reviews at least quarterly will also be an automatic default.*
 - *Additionally, other beneficiary interventions may be provided.*
- *Provide the specific prescriber interventions:*
 - *This will automatically default to prescriber interventions to resolve medication-related problems or optimize therapy.*
 - *Selections must be provided for the delivery method(s) for the prescriber consultation.*
 - *Additionally, other prescriber interventions may be provided.*
- *Provide a detailed description of how your program will provide the MTM interventions for both beneficiaries and prescribers, including the annual comprehensive medication review for the beneficiary, which includes a review of medications, interactive, person-to-person consultation, and an individualized, written summary of interactive consultation, and quarterly targeted medication reviews.*
- Resources and who will provide MTM services.
 - *Provide the type of personnel that will be providing the MTM services such as in-house staff or the type of outside personnel.*
 - *Provide the type of qualified provider such as pharmacist, physician, or registered nurse.*
- 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.
 - *Provide if fees are covered as part of the services of the global **Pharmacy Benefits Manager (PBM)** or vendor contract (without being priced out separately) or if fees are priced out separately.*
 - *If the fees are priced out separately and 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.*
 - *Provide the specific fee(s), billing method(s) such as per minute or per service. A description of these fees may also be included.*
- Methods of documenting and measuring outcomes.

Provide the outcomes measured.

30.7 – MTMP Approval Considerations ***(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)***

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.).
- *The plan will consider the provision of the other prescription drug quality improvement interventions to beneficiaries who do not meet all three of the required MTMP criteria as described by the plan, however, these cannot be considered for MTM reimbursement by CMS.*
- *Plans will promote continuity of care by performing an end-of-year analysis that identifies current MTM program participants who will continue to meet the eligibility criteria for the next program year for the same plan.*
- *Plans will have procedures in place to drive participation and follow-up with beneficiaries that do not respond to initial offers for MTM services.*
- *Plans will consider using more than one approach when possible to reach all eligible patients who may wish to receive MTM services.*
- *Plans will analyze and evaluate their MTMP and make changes to continuously improve their programs.*

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.

30.8 – *Mid-Year MTMP Changes*

(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

*Once an MTMP is approved by CMS during the Annual Review, limited changes to the Part D sponsors' MTMP may be allowed in accordance with CMS policy. To promote evolving MTM best practices and to serve the best interests of the Medicare beneficiary, CMS allows certain mid-year changes to Part D sponsors' approved MTMPs during three Update Cycle windows: **March 1-March 10, June 1-June 10, and September 1-September 10.** 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:
 - *Frequency of-* identification *of potential enrollees* 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.

*MTMP requests for changes during the program year may be submitted to CMS during **any of the three Update Cycle windows: March 1-March 10, June 1-June 10, and September 1-September 10.** Requests for changes to an approved MTMP that would be effective for an upcoming program year should be submitted to CMS during the **September 1-September 10** update cycle window.*

The MTMP change request should be submitted through the HPMS in the MTMP submission module under “Plan Formularies.” This interface was established to enable Part D sponsors to enter, edit, and submit their MTMP descriptions within HPMS at the contract level. The ‘MTMP Change Request Form’ is now integrated within the enter/edit function of the MTMP submission module for the Update Cycles. The MTMP submission gates to enter/edit the MTMP will automatically be open during the Update Cycle windows. For any submissions made in the Update Cycles due to updates, required resubmissions, and contract exceptions, a sponsor is required to enter information in the Change Request Form Description field(s) to justify the change on the Enter/Edit pages and check the attestation, “I attest that the following change(s) 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” on the Verify Submission page.

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

30.9 – MTMP Reporting *(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)*

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.

Consistent with CMS's 2010 Part D reporting requirements, Part D sponsors must measure and report, at the beneficiary level, the number of CMRs, the number of targeted medication reviews, number of prescriber interventions, and the change(s) in therapy directly resulting from the MTM interventions.

For more information about these reporting requirements, see Appendix A for the MTMP Web page.

30.10 – Claims Processing for MTM Services ***(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)***

For MTM claims processing, covered entities should use the American Standards Committee (ASC) X12 837P Version 4010/4010A1. CMS articulated in its 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. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

Part D sponsors are required to establish electronic prescription drug programs to provide for electronic transmittal of certain information to the prescribing provider and the dispensing pharmacy and pharmacist. There is no requirement that prescribers or dispensers implement e-prescribing. However, prescribers and dispensers who electronically transmit prescription and certain other prescription-related information for Medicare Part D covered drugs prescribed for Medicare Part D eligible individuals are required to comply with any applicable final standards that are in effect.

Part D sponsors should ensure that their pharmacy contracts require compliance with the Part D e-prescribing standards whenever the network pharmacy electronically receives or transmits prescriptions or prescription-related information about Part D covered drugs that are prescribed to Part D eligible individuals. Although Part D sponsors are not required to pay for standard e-prescribing transactions between prescribers and network pharmacies, such e-prescribing transaction costs incurred by their network pharmacies are legitimate Part D overhead costs that should be a consideration in setting network dispensing fees.

The Medicare Modernization Act (MMA) required the identification of potential e-prescribing standards, which the Secretary would recognize as “initial uniform standards.” These standards would generally be subject to pilot testing prior to the promulgation of final uniform standards. This general requirement was to be waived, however, in instances in which there was “adequate industry experience” with an initial standard.

*The Secretary recognized a number of initial standards. Three met the requirements for adequate industry experience. The “E-Prescribing and the Prescription Drug Program” final rule, which was published in the Federal Register on November 7, 2005, (70 FR 67568) adopted *these* “foundation e-prescribing standards.” CMS refers to them as “foundation standards” because they *were the first set of final standards adopted for the Part D e-prescribing program. As subsequently amended (see, 73 FR 18918) the foundation standards are as follows:**

1. Prescription standards.

On or after April 1, 2009, The National Council for the Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, (Version 8.1) 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.

Six other initial standards were pilot tested. Based upon the evaluation of the pilot project and public comments CMS issued *the Standards for E-Prescribing Under Medicare Part D* final rule (73 FR 18918) adopting *four* additional e-prescribing standards with which Part D sponsors' e-prescribing programs must also comply. These *four* standards are:

1. 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).

2. *Prescription Fill Status Notification (RxFill)*

- *To provide for the communication of prescription fill status between prescribers and dispensers—*

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

3. 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.

This standard includes five separate files for providing formulary or benefit information to the prescriber:

*Formulary Status List
Formulary Alternatives List
Benefit Coverage List
Benefit Copay List
Drug Classification List*

Part D sponsors must be capable of sending all of these files electronically using the adopted standard if such information is requested, including all conditional fields for all these files if such information is requested by prescribers.

4. 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.

In order to monitor the uptake of e-prescribing in the Part D program, Part D sponsors are required to obtain the Prescription Origin Code via the NCPDP Telecommunication Standard 5.1 optional field 419 DJ and report this code on their prescription drug event (PDE) submissions. A corresponding Prescription Origin Code field has been added to the PDE record file layout and PDE return file layout at field number 41.

CMS requires the Prescription Origin Code (using alphanumeric values 1-4) only on PDEs for new prescriptions submitted in Standard format (currently Standard format is NCPDP Telecommunication Standard 5.1). The Prescription Origin Code will remain optional for all PDEs for refills submitted in the Standard format and for all PDEs submitted in the Non-Standard Format. Further, the Part D sponsor has the options to report “blank” for PDEs for refills and Non-Standard format PDEs.

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.ncdp.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. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

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 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 *general drug* 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. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

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 (*i.e., step therapy and quantity limits*). 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.

Instructions at 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 – Website Posting Requirements

(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

Part D sponsors must post their approved PA criteria (including PA criteria applied to *supplemental* drugs provided by enhanced alternative plans), *quantity limit restrictions and step therapy requirements on plan Web sites*. 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 *all approved utilization management (UM)* 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 *UM* is displayed or from a general link on the formulary page. Part D sponsors will be expected to display all of the *UM* criteria content contained within the CMS approved HPMS files without modification. Minor grammatical changes will be permitted for display purposes in cases where abbreviations or grammatical errors occurred due to HPMS 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. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

In accordance with 42 CFR 423.564, Part D sponsors must provide meaningful procedures for timely hearing and resolving enrollee grievances. Chapter 18 of *this* manual (see Appendix A for Web site) defines a grievance as any complaint or dispute 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 *as part of their Part D reporting requirements*. 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. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

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. *Complaints categorized as “urgent need” should be resolved within 7 calendar days of receipt; and complaints without an immediate or urgent designation should be resolved within 30 days of receipt.*¹²

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% *of cases designated as “immediate need” resolved within 2 calendar days of receipt* 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.

¹ *CMS reserves the right to classify any complaint as “Immediate Need” or “Urgent” if it doesn’t meet the standard guidelines for these types of complaints (such as access to care or lack of medications) should the complaint be egregious in nature. An egregious complaint would mean that there is potential for harm or hardship to the beneficiary.*

² *The resolution time period begins on the initial assignment/reassignment date into CTM. Friday complaints are loaded into CTM on Saturday; weekend complaints are loaded into CTM on Monday.*

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_ReportingOveright.asp

FDA Medwatch Reporting

<http://www.fda.gov/medwatch>

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R11PDB	02/19/2010	Chapter 7-Medication Therapy Management and Quality Improvement Program	03/01/2010	N/A
<u>R3PDB</u>	09/05/2008	Initial release of chapter	09/01/2008	N/A