MEDICARE MODERNIZATION ACT FINAL GUIDELINES -- FORMULARIES
CMS Strategy for Affordable Access to Comprehensive Drug Coverage
Guidelines for Reviewing Prescription Drug Plan Formularies and Procedures

1. Purpose of the Guidance

This paper is final guidance on how CMS will review Medicare prescription drug benefit plans to assure that beneficiaries receive clinically appropriate medications at the lowest possible cost. Two key requirements in the Medicare Modernization Act (MMA) are to assure that drug plans provide access to medically necessary treatments for all and do not discriminate against any particular types of beneficiaries, and to encourage and support the use of approaches to drug benefit management that are proven and in widespread use in prescription drug plans today. The goal is for plans to provide high-quality cost-effective drug benefits by negotiating the best possible prices and using effective drug utilization management techniques. This goal can be achieved through a CMS drug benefit review strategy that facilitates appropriate beneficiary access to all medically necessary Part D covered drugs along with plan flexibility to develop efficient benefit designs, thus bringing drug benefit strategies that are already providing effective coverage to millions of seniors and people with a disability to the Medicare population. Our formulary review process focuses on three areas:

1. Pharmacy and Therapeutics (P&T) committees. CMS will require P&T committees to rely on widely-used best practices, reinforced by MMA standards. CMS oversight of these processes will assure that plan formularies are designed to provide appropriate, up-to-date access for beneficiaries and give plans the flexibility to offer benefit designs that provide affordable access to medically necessary drugs.

2. Formulary lists. CMS' review of plan formularies will look to best practices in existing drug benefits serving millions of seniors and people with disabilities to ensure appropriate access for Medicare beneficiaries. CMS will evaluate formulary classification systems as well as the actual list of drugs included in the formulary, using existing widely used classification systems and drug plans as checks.

3. Benefit management tools. CMS will compare plans' use of benefit management tools, like prior authorization, to the way these tools are used in existing drug plans, to ensure that they are being applied in a clinically appropriate fashion. We have protected beneficiary rights by putting appropriate appeals and exceptions standards in the final regulations and by reviewing processes that plans use to provide timely access. In developing this approach, CMS has looked to existing national drug benefit management standards and guidelines that underlie drug plans that are currently providing effective coverage, as well as a variety of examples of such drug plans.

CMS has developed the final rule for the new Medicare drug benefit based on extensive public comments on how best to provide access to up-to-date medical treatments for all beneficiaries at the lowest possible cost. This paper sets forth the approach that will be used in conjunction with the final regulation to promote transparency, predictability, and effective implementation of the law in conjunction with our final rule.

2. Background

The addition of a prescription drug benefit to Medicare as a result of the MMA represents a landmark change to the Medicare program, a change that will significantly improve the healthcare coverage available to millions of Medicare beneficiaries. In the final regulation, we have included policies, such as formulary requirements and exceptions and appeals processes, to assure that beneficiaries have access to covered drugs that are medically necessary for their condition while enabling plans to design and manage their formularies to provide the most affordable benefit possible. We are also adjusting the payments to drug plans based on the expected costs of their enrollees, as well as implementing many other steps to limit the financial risk facing drug plans. Together, our goal is to provide a foundation for fair competition to offer high-quality coverage at the lowest cost to all types of Medicare beneficiaries, and to reward plans that focus on this critical policy goal.

The MMA is designed to encourage prescription drug plans and Medicare Advantage prescription drug plans that meet the law's requirements to offer comprehensive prescription drug plan options for Medicare beneficiaries by providing flexibility for plan design and management. This flexibility is modeled after the way most Americans, including millions of seniors and people with disabilities, receive drug benefits today through federal and private-sector retiree coverage, as well as State Medicaid programs. How much beneficiaries save depends on how a plan's formulary is structured and the benefit is operated. The goal of this program, however, is not to save money on prescription drug costs at the expense of appropriate medical care. Appropriate medical care would not be possible if plans actively sought to discourage enrollment by beneficiaries with high, expected drug costs.

Consequently, CMS seeks to implement a strategy to ensure that formularies and utilization management tools are consistent with effective practices in drug benefit management today, in conjunction with many other steps we are implementing to appropriately compensate plans for covering beneficiaries with relatively high expected drug costs. CMS oversight will ensure that Part D plans operate in accordance with this strategy. We will compare proposed Part D formularies using current best practices for developing and maintaining a formulary's drug categories and classes, and will support the use of USP model categories and classes for plans that choose to use them (plans are not required to do so). However, because drug classes alone, whether detailed or general, are not sufficient to determine whether beneficiaries have adequate access, we also will review the drug plans' formularies and benefits to identify discriminating practices. Under Section 1860D-11(e)(2)(D) of the Social Security Act, a plan design will be approved only if "the Secretary does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan." Thus, even if CMS concludes

that a plan's therapeutic categories and classes are robust, our review may find the plan design violates this statutory provision if some other aspect of the plan's benefit design is problematic.

CMS intends to encourage and approve formularies and benefit management approaches that are already in widespread use to provide drug coverage to millions of seniors and people with disabilities today. We will consider the structure and use of an organization's P&T committee, as well as the structure of the formulary and the policies and procedures for providing access to both formulary and non-formulary drugs. Since drug utilization management activities are as important as the list of drugs in the formulary in providing access to high quality pharmaceutical care for all categories of beneficiaries, we will use checks based on commonly-used best practices to review those policies and procedures to ensure beneficiary access to Part D covered prescription drugs that are medically necessary for their course of treatment. Approved formularies for Part D contractors will be available for beneficiaries in time for them to consider their options prior to enrollment. We anticipate that drug plans that follow commonly used best practices will have little difficulty with these checks.

3. Guiding Principles for CMS Formulary and Benefit Review Strategy

A formulary is more than a list of approved medications. A formulary must consist of drugs that will provide patients with a clinically appropriate medication for the course of treatment established by the physician. Consistent with industry standards/practices, the formulary is supported by a system of care management tools to consistently provide patients with access to medications that have been demonstrated to be safe, effective, and affordable, while maintaining and improving quality patient care. To ensure that Medicare prescription drug plans are following best practices, the CMS formulary review will follow four important principles.

Principle #1 – Rely on Existing Best Practices: CMS' review will rely on widely recognized best practices for existing drug benefits serving millions of seniors and people with disabilities, to ensure appropriate access for Medicare beneficiaries.

Principle #2 -- Provide Access to Medically Necessary Drugs: We will require that drug plans provide access to Part D drugs determined to be medically necessary.

Principle #3 -- Flexibility: CMS will allow plans to be flexible in their benefit designs to promote real beneficiary choice while protecting beneficiaries from discrimination.

Principle #4 – Administrative Efficiency: CMS will develop a streamlined process to conduct effective reviews of plan offerings within a compressed period of time.

4. Strategic Approach

A. P & T Committee Review

We believe that current best practices for P&T committees should be applied when developing and administering P&T committees for the Medicare drug benefit. Incorporating best practice philosophies, along with inclusion of the MMA requirements, allows for a drug benefit that is clinically robust.

Rationale

CMS oversight of the P&T committee process is an important requirement of the MMA to ensure plans offer a comprehensive drug benefits. Operated under appropriate guiding principles, a P&T committee is a forum for an evidence-based formulary review process that establishes policies on the use of drug products and therapies, and identifies drug products and therapies that are medically appropriate and cost-effective. P&T committees must meet best practices consistent with those contained in several widely accepted guidelines for P&T management. CMS standards and guidelines for the P&T activities will help ensure that formulary decisions are based on scientific and economic considerations that achieve appropriate, safe and cost effective drug therapy, and that the P&T committee has a key role in defining policies for utilization management activities such as access to non-formulary drugs, prior authorization, step therapy, quantity limitations, generic substitution, and therapeutic interchange protocols to assure that products and therapies, such that these tools are used to drive medically appropriate and cost-effective access to Part D covered drugs. The P&T committee will also be expected to analyze and recommend, where appropriate, regional variations of national best practices.

These standards will be clearly articulated in the plan applications and our contracts with Medicare prescription drug plans. They will also be integrated into the CMS management and oversight of Part D plans after January 2006, to assure that the P&T rules are maintained and followed.

Approach

CMS will require that plans assure the implementation and use of a P&T committee consistent with the pharmacy benefit management principles outlined and expressed by the American Society of Health System Pharmacists (ASHP Statement on the Pharmacy and Therapeutics Committee, Am J Hosp Pharm. 1992, *http://www.ashp.org/bestpractices/formulary-mgmt/Form_St_PTComm.pdf*), or the Principles of a Sound Drug Formulary System October 2000, *www.amcp.org* , a consensus document endorsed by the Academy of Managed Care Pharmacy, American Association of Retired Persons, the Alliance of Community Health Plans, the American Medical Association, the American Society of Health-System Pharmacists, the Department of Veteran Affairs, the National Business Coalition on Health, and the U.S. Pharmacopeia.

The requirements listed below are represented as 'BP' for best practice (or Industry Standard Practice) where they have been drawn from commercial best practices consistent with these nationally recognized P&T guidelines, and are represented as 'MMA' where the requirements support the unique provisions of the MMA.

Membership

- P&T committee members must represent various clinical specialties that adequately represent the needs of plans beneficiaries (i.e., include representation of "high volume specialists" in the standard terminology of the industry). (BP)
- A majority of the P&T committee members must be practicing physicians, practicing pharmacists or both. (BP)
- At least one P&T committee practicing pharmacist and one practicing physician must be experts in the care of elderly or disabled persons. (MMA)
- At least one P&T committee practicing pharmacist and one practicing physician must be independent and free of conflict with respect to the plan and pharmaceutical manufacturers. (MMA)

Conflict of Interest

- P&T committee members should sign a conflict of interest statement revealing economic or other relationships with entities affected by drug coverage decisions that could influence committee decisions. (BP)

Meeting Administration

- P&T committee should meet on a regular basis, and not less frequently than on a quarterly basis. (BP)
- P&T committee decisions regarding formulary development or revision must be documented in writing. (BP)

Formulary Management

- P&T committee must review for clinical appropriateness, the practices and policies for formulary management activities, such as prior authorizations, step therapies, quantity limitations, generic substitutions and other drug utilization activities that affect access. (BP)
- Formulary management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe and cost effective drug therapy. (BP)
- The P&T committees will be required to establish and document procedures to assure appropriate drug review and inclusion. (BP)
- Clinical decisions by the P&T committee should be based on scientific evidence and standards of practice, including peer reviewed medical literature, well-established clinical practice guidelines and pharmacoeconomic studies as well as other sources of appropriate information. (BP)
- Drugs' therapeutic advantages in terms of safety and efficacy must be considered when selecting formulary drugs and placing them into formulary tiers. (MMA)
- The P&T committee will make a reasonable effort to review a new chemical entity within 90 days, and will make a decision on each new chemical entity within 180

days of its release onto the market, or a clinical justification will be provided if this timeframe is not met. These timeframes also include the review of products for which new FDA indications have been approved. We set this timeframe in response to public comment on our proposed guidance, but note that plans must make access to new drugs available to enrollees when medically appropriate via exceptions processes even before this deadline. (BP)

- P&T committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis. (MMA)
- Formulary therapeutic categories and classes may be changed only at the beginning of each plan year or when new drugs or new drug therapeutic uses appear. (MMA)

Formulary Exceptions

- P&T committees must review for clinical appropriateness protocols and procedures for the timely use of and access to both formulary and non-formulary drug products. A non-formulary drug may be needed, for example, when the formulary drug would cause adverse effects or would not be as effective or both, based on scientific evidence or medical necessity. (BP)

B. Formulary List Review

Rationale

The formulary list review will incorporate best practices from the private sector, Medicaid and FEHB formularies. The MMA requires CMS to review Part D formularies to ensure that beneficiaries have access to a broad range of medically appropriate drugs to treat all disease states and to ensure that the formulary design does not discriminate or substantially discourage enrollment by certain groups. We expect that the kinds of formularies in widespread use today, which provide high-quality drug coverage to millions of Medicare beneficiaries, would receive a straightforward approval under this approach with modifications to account for specific features of Medicare's benefit structure, (i.e., including home infusion products that may not be covered under a pharmacy benefit in commercial benefit designs). Plans may also have to make modifications to existing commonly used formularies to allow for coverage of commonly-used vaccines and diabetic supplies as outlined in the MMA. Below we provide a series of checks that CMS will use to confirm that plan formularies will provide the kind of effective, non-discriminatory access available in drug benefit plans today.

Approach

We encourage plans to submit formularies similar to those in widespread use today. We will check the formulary to ensure inclusion of a range of drugs in a broad distribution of therapeutic categories and classes, to satisfy the MMA requirement that a plan's categorization system does not discourage enrollment to any group of beneficiaries. We also will consider the specific drugs, tiering and utilization management strategies employed in each formulary. CMS will identify outliers from common benefit management practices for further evaluation. Plans may be asked to provide written clinical justification for unusual benefit features that are deemed as outliers.

Review of Categories and Classes

We will review all classification systems to assure that plans provide an appropriate breadth of categories and classes that cover all disease states. CMS will not consider a classification system in isolation from the subsequent steps in our formulary review; a classification system with a smaller number of classes may be acceptable if it nonetheless provides preferred access to a relatively broad range of widely used medicines.

As described in the MMA, plans that utilize a classification system that is consistent with the USP classification system, available at *http://www.usp.org/pdf/drugInformation/mmg/finalModelGuidelines2004-12-31.pdf*, will satisfy a safe harbor and thus CMS will approve their formulary classification system. For plans that choose to adopt an alternative to USP's classification structure, CMS will check the plan's proposed classification system to determine if it is similar to USP or other commonly used classification systems, such as the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification, information available at *www.ashp.org/ahfs*.

The minimum statutory requirement is that a formulary must include at least two drugs in each approved category and class (unless only one drug is available for a particular category or class), regardless of the classification system that is utilized. We view this requirement as a floor rather than an absolute standard. CMS may require more than two drugs per category or class in cases where additional drugs present unique and important therapeutic advantages in terms of safety and efficacy, and their absence from the plan formulary may substantially discourage enrollment in the plan by beneficiaries with certain disease states.

Even though a formulary may pass the classification review and have a safe harbor for its categories and classes, it still must undergo the drug list review and benefit management tools review in order to analyze the depth and breadth of drugs and their restrictions.

Drug List Review

Regardless of the classification system chosen, CMS will review and approve drug lists that are consistent with best practice formularies currently in widespread use today. The following paragraphs describe the multiple checks that will be utilized as part of the drug list review.

1. CMS will review formularies for at least one drug in each of the *Formulary Key Drug Types* identified by USP as Attachment B in comments provided to CMS on the draft formulary guidance, available at: *http://www.usp.org/pdf/drugInformation/mmg/attachmentstoUSPComments2004-12-30.pdf*. Best practice formularies commonly include at least one drug in each of the *Formulary Key Drug Types* as a minimum on their formulary. Plans may present a reasonable clinical justification for formularies that do not contain at least one drug for each of the USP *Formulary Key Drug Types*.

2. CMS will review tier placement to provide an assurance that the formulary does not discourage enrollment of certain beneficiaries. When developing their formulary tier structure, plans should utilize standard industry practices. Tier 1 should be considered the lowest cost-sharing tier available to beneficiaries. Any and all subsequent tiers within the formulary structure will be higher cost-sharing tiers in ascending order. For example, drugs in Tier 3 will have a higher cost-share for beneficiaries than drugs in Tier 2. Best practices in existing formularies and Medicaid preferred drug lists generally place drugs in a less preferable position only when drugs that are therapeutically similar (i.e., drugs that provide similar treatment outcomes) are in more preferable positions on the formulary. The CMS review will focus on identifying drug categories that may discourage enrollment of certain beneficiaries by placing drugs in non-preferred tiers in the absence of commonly used therapeutically similar drugs in more preferred positions.

3. CMS will analyze formularies to determine whether appropriate access is afforded to drugs addressed in the following widely accepted national treatment guidelines which are indicative of general best practice: asthma, diabetes, chronic stable angina, atrial fibrillation, heart failure, thrombosis, lipid disorders, hypertension, chronic obstructive pulmonary disease, dementia, depression, bipolar disorder, schizophrenia, benign prostatic hyperplasia, osteoporosis, migraine, gastroesophageal reflux disease, epilepsy, Parkinson's disease, end stage renal disease, hepatitis, tuberculosis, community acquired pneumonia, rheumatoid arthritis, multiple sclerosis and HIV. This list of conditions does not represent an exhaustive list, but merely serves as another check in the review process. Drugs or drug classes included within these widely accepted guidelines will not place undue burden on plans since these drugs are usually placed in favorable positions on commonly used, best practice formularies.

4. CMS will use Medicare risk adjustment data to check proposed formularies to determine whether the formularies include drugs that are most commonly used by the Medicare population and are reflected across the Drug Hierarchical Condition Categories (DHCC) used to determine Medicare risk adjustment. These DHCCs are representative of more than 5,000 ICD-9 diagnostic codes. For each DHCC, both the inclusion of the drug and its tier position will be checked against other Part D formularies and commonly used drugs in the overall Medicare population, to avoid drug selection and cost-sharing that discriminate against specific disease groups.

5. CMS' expectations are that best practice formularies contain a majority of drugs within the following classes: antidepressants, antipsychotics, anticonvulsants, antiretrovirals, immunosuppressants, and antineoplastics. Following common best practices, CMS will check to see that beneficiaries who are being treated with these classes of medications have uninterrupted access to all drugs in that class via formulary inclusion, utilization management tools, or exceptions processes. When medically necessary, beneficiaries should be permitted to continue utilizing a drug that is providing clinically beneficial outcomes. In cases where practices may deviate from the above, plans must provide clinical documentation to justify their decisions.

6. CMS will analyze the availability and tier position of the most commonly prescribed drug classes for the Medicare population in terms of cost and utilization (Appendix A). This list is derived from the Medicare Current Beneficiary Survey (MCBS) data from 2002. CMS understands that plans will not provide identical coverage of these drug classes, and our review will focus on assuring that plans present a balanced formulary. These drug classes will cover common diseases and conditions, and will allow us to ensure that plans are covering the most widely used medications, or therapeutically similar medications, for the most common conditions.

All formularies will be evaluated using the criteria outlined above. Outliers for each area of review will be further evaluated by CMS to determine if the outlier is deemed potentially discriminatory. Examples of this may include a lack of appropriate drug classes to treat certain diseases, a lack of sufficient drugs in a therapeutic class, inappropriate tier placement that would discriminate against a group of beneficiaries, or missing drugs that would cause discrimination. If any of the outliers appear to create problems of access, plans will have the opportunity to present reasonable clinical justifications.

Long Term Care Accessibility

Part D plans will be required to provide medically necessary prescription drug treatments to LTC facility residents. Well in advance of the application deadline, CMS will provide additional LTC guidance that will reflect standard practices in LTC pharmacies.

C. Review of Benefit Management Tools that Affect Access

Rationale

CMS will review plans' use of utilization management tools, including prior authorization, step therapy, quantity limitations, and generic substitution to ensure that beneficiaries are given appropriate access to drugs in a timely manner. We will also review plans' drug utilization review procedures and appeals, exceptions and grievances processes. Our review will focus on ensuring that these plan systems reflect best practices that are commonly utilized in the private sector, Medicaid and FEHB plans.

Approach

Prior Authorization, Step Therapy, Quantity Limitations, Generic Substitution

CMS will look to existing best practices to check that plans' use of these utilization management tools is consistent with such practices. We will look to current industry standards as well as appropriate guidelines that might be found from expert organizations such as NCQA, AMCP, and NAIC, and to the use of such standards in existing drug plans that are widely used by seniors and people with disabilities. CMS will assure that

plans' use of such tools is consistent with best practices. CMS will also compare formularies amongst the applicants to analyze the comparative use of practices such as prior authorization, step therapy, and quantity limits. Our expectation is that these techniques will be used in Part D formularies consistently with the way they are applied in existing formulary systems, both in terms of the situations in which they are used and the timeliness of the processes. In cases where a plan may fall outside of best practices, the plan will be asked to provide a reasonable justification for their practices.

Drug Utilization Review (DUR)

CMS will review plans' DUR practices to confirm that they meet industry best practices in terms of access to drugs and quality oversight. We will expect plans' use of tools and techniques currently in place in their commercial coverage business. These processes may include concurrent review as well as prospective and/or retrospective utilization review. These reviews will be expected to assure appropriate access to medically necessary therapies as well as guard against inappropriate or dangerous utilization of prescription medications.

Appeals, Exceptions and Grievances

The standards for handling appeals, exceptions, and grievances are specific and are contained in the final rule. We believe the final rule reflects current best practices around appeal and grievance timeframes. We are developing notice requirements to ensure that beneficiaries understand their rights in this area. We also expect to require standardized reporting from Part D plans on denial, reconsideration and appeals, and exceptions processing, and we will use these data in our management and oversight activities. We expect plans to make appropriate use of the data for internal quality initiatives, such as those directed at managing excessive rates of overturned utilization management decisions. Part D plan sponsors that provide prescription drug benefits for Part D drugs and manage this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination.

5. Formulary Submission Requirements

In support of the Medicare Modernization Act (MMA), CMS is establishing a systems interface within the Health Plan Management System (HPMS) to enable MA-PD plans and PDPs to submit their formularies electronically. This functionality will provide for the upload and receipt of the formulary file, exceptions and notes file, prior authorization supplemental data and step therapy supplemental data, as defined by CMS. It will also allow CMS to provide more timely, systematic, and consistent feedback to plans regarding their formulary practices.

Using the HPMS formulary upload module, the user will submit one or more formulary files for the MA-PDs or PDPs offered under a contract. This submission must occur prior to April 18, 2005 at 5:00pm EDT. Detailed technical user instructions will be forthcoming. The general

process that the user will complete in order to submit their plan's drug formulary information includes the following steps:

- General formulary-level data entry in a designated HPMS web page
    - Plan will be required to complete data entry in an HPMS web interface for information such as Plan name , formulary name, classification structure used, etc.

- Attachment of an NDC-level Formulary file in a flat file text format
    - Plan will attach their Formulary file submission. The Formulary file will be created as a flat file in ASCII format by the MA-PD or PDP outside of the HPMS prior to submission. The file must be created using National Drug Codes (NDCs) as a proxy for drug name. Appendix B illustrates the required data fields for each NDC record in the Formulary file.

- If relevant, attachment of a Step Therapy Algorithm file in MS-Word format
    - During the general formulary-level data entry process, the user will be asked if the NDCs in the formulary submission are associated with one or more Step Therapy management programs. If the drugs in the formulary submission are associated with Step Therapy management programs, then the user is required to submit an attachment that provides the detailed algorithms for all Step Therapy management programs in the formulary. The Step Therapy Management Algorithm file should be submitted in HPMS as a Word file. The user should submit only one Step Therapy Management Algorithm file attachment per formulary file submission.

- If relevant, attachment of a Prior Authorization Criteria file in MS-Word format
    - During the general formulary-level data entry process, the user will be asked if the NDCs in the formulary submission are subject to prior authorization. If the drugs in the formulary submission are associated with prior authorization, then the user is required to submit an attachment that provides the detailed criteria for all prior authorization programs. The Prior Authorization Criteria file should be submitted in HPMS as a Word file. The user should submit only one Prior Authorization Criteria file attachment per formulary file submission.

- If relevant, attachment of an Exceptions and Formulary Notes file in MS-Word format
    - The user will have the ability to attach a Word file that provides additional details about any exceptions associated with the Formulary file. For example, when a particular dosage form or strength has restrictions, such as prior authorization or unique quantity limits, then the user should note these exceptions in a Word attachment (e.g. Imitrex injection vs. tablets). Plan must also include in the notes section, an explanation of its entire exceptions process.

Information concerning formularies will be made publicly available at some point prior to the beneficiary enrollment period. Applicants can always seek to protect their information under the Freedom of Information Act and label truly proprietary information "confidential" or "proprietary." When information is so labeled, the Applicant is required to explain the

applicability of the FOIA exemption they are claiming. When there is a request for information that is designated by the Applicant as confidential or that could reasonably be considered exempt under Exemption 4, CMS is required by its FOIA regulation at 45 C.F.R. §5.65(d) and by Executive Order 12,600 to give the submitter notice before the information is disclosed. To determine whether the Applicant's information is protected by Exemption 4, the Applicant must show that— (1) disclosure of the information is likely to impair the government's ability to obtain necessary information in the future; (2) disclosure of the information is likely to cause substantial harm to the competitive position of the submitter; or (3) the records are considered valuable commodities in the marketplace which, once released through the FOIA, would result in a substantial loss of their market value. Consistent with our approach under the Medicare Advantage program, we would not release information under the Medicare Part D program that would be considered proprietary in nature.

6. Formulary Maintenance Requirements

Under the MMA, plans may only change therapeutic categories and classes at the beginning of each plan year unless new drugs or new therapeutic uses appear. However, plans must submit changes to the formulary (additions, deletions or tier changes) as they occur. CMS will accept changes to formulary drugs on a regular basis, within 30 days after a P&T committee makes decisions. Plans shall submit any formulary drug list changes between the 1st day and the 7th day of each month, beginning November 1, 2005. These submitted changes will be reviewed by CMS to ensure that formularies remain nondiscriminatory and meet other minimum standards. The effective dates of submitted formulary changes are subject to the time periods outlined in the final rule.

Appendix A

Top Drug Classes by Cost and Utilization

Top Drug Classes by Cost and Utilization	
ACE inhibitors	Nitrates
Alpha blockers	Non-sedating antihistamines
Angiotensin receptor blockers	Opioids
Anticoagulants	Opioid / analgesic
Antigout	Platelet aggregation inhibitors
Atypical antipsychotics	Potassium
Beta-blockers	Potassium sparing diuretic / thiazide diuretic
Biguanides	Ophthalmic prostaglandins
Bisphosphonates	Proton pump inhibitors
Calcium channel blockers	Quinolones
Calcium channel blocker / ACE inhibitor	Sedatives
Cardiac inotropes	Selective estrogen receptor modifier
Cholinesterase inhibitors	Short-acting beta agonists
Corticosteroids	SSRIs
Cox-2 inhibitors	Statins
Estrogen replacement	Sulfonylureas
GABA Agents	Thiazide diuretics
Leukotriene modifiers	Thiazolidinediones
Long-acting beta agonist / inhaled corticosteroid	Thyroid replacement
Loop diuretics	Tricyclic antidepressants

Appendix B

Draft Formulary File Record Layout

Required File Format = ASCII File

Field Name	Field Type	Field Length	Field Description	Sample Field Value(s)
NDC	CHAR NOT NULL	11	11-Digit National Drug Code	00000333800
Tier_Level_Value	CHAR NOT NULL	2	Defines the Cost Share Tier Level Value Associated with the NDC. Assumption is that the NDC is assigned to one tier value. These values are consistent with the selection of value options available to data entry users in the Plan Benefit Package software. If no Tier Level Value applies, enter '1' as the value for this field.	1 = Tier Level 1 2 = Tier Level 2 3 = Tier Level 3 4 = Tier Level 4 5 = Tier Level 5 6 = Tier Level 6 7 = Tier Level 7 8 = Tier Level 8 9 = Tier Level 9 10 = Tier Level 10
Drug_Type_Label_Value	CHAR NOT NULL	1	Define the Drug Type Label Value for the NDC. Enter the label value for the Drug Type from the defined list of labels in the instructions. If Drug Type Label Value 6 = "Other" is used, then the user must describe the "Other" label description in the Drug_Type_Label_Value_Other field.	1 = Generic 2 = Preferred Brand 3 = Non-Preferred Brand 4 = Non-Formulary 5 = Specialty 6 = Other
Drug_Type_Label_Value_Other	CHAR NULL	50	Describe the "Other" label description. If "Other" does not apply, leave this field blank.	Orphan
Quantity_Limit_Amount_YN	CHAR NOT NULL	1	Does the NDC have a quantity limit other than a 30-day or 34-day limit?	1 = Yes 0 = No

Quantity_Limit_Amount	NUM NULL	3	If Yes to Quantity_Limit_Amount_YN, enter the quantity limit unit amount. The units for this amount may be defined as number of pills, number of injections, etc. If a limit other than 30 or 34 days does not apply, leave this field blank.	9
Quantity_Limit_Days	NUM NULL	3	Enter the days associated with the quantity limit. If a limit other than 30 or 34 days does not apply, leave this field blank.	60 (e.g., 9 pills every 60 days) (e.g., 9 injections every 60 days)
Prior_Authorization_YN	CHAR NOT NULL	1	Is prior authorization required for the NDC?	1 = Yes 0 = No
Therapeutic_Category_Name	CHAR NULL	100	If the Category/Class Database Source is indicated as "OTHER" in the HPMS Data Entry Web Interface (i.e., neither USP nor AHFS is used by the plan), then the user should enter the Therapeutic Category Name for each NDC in the file. If the drug is based on either USP or AHFS Therapeutic Category Classes, then leave this field blank.	Analgesics
Therapeutic_Class_Name	CHAR NULL	100	If the Category/Class Database Source is indicated as "OTHER" in the HPMS Data Entry Web Interface (i.e., neither USP nor AHFS is used by the plan), then the user should enter the Pharmacological Class Name for each NDC in the file. If the drug is based on either USP or AHFS Pharmacological Classes, then leave this field blank.	Opioid Analgesics
Formulary_Key_Drug_Type_Name	CHAR NULL	100	*OPTIONAL*: If the Category/Class Database Source is indicated as "OTHER"	Opioid Analgesics, long-acting

			in the HPMS Data Entry Web Interface (i.e., neither USP nor AHFS is used by the plan), then the user has the option to enter the Formulary Key Drug Type (subdivision) Name for each NDC in the file. If the drug is based on either USP or AHFS, then leave this field blank.	
Step_Therapy_Type_Group_Num	NUM NULL	1	Number of step therapy drug treatment groups, in which the NDC is included. If Step Therapy does not apply to this drug, then leave this field blank.	3
Step_Therapy_Type_Group_Desc_X	CHAR NULL	100	Description of step therapy drug treatment group. Field should be repeated in the record based upon number of groups declared in Step_Therapy_Type_Group_Num If Step Therapy does not apply to this drug, then leave this field blank.	Step_Therapy_Type_Group_Desc_1 = "CH Therapy" Step_Therapy_Type_Group_Desc_2 = "An Therapy" Step_Therapy_Type_Group_Desc_3 = "CV Therapy"
Step_Therapy_Type_Group_Step_X	CHAR NULL	3	Step number within the sequence for the Step Therapy Group. Field should be repeated in the record based upon number of groups declared in Step_Therapy_Type_Group_Num AND in the same order as Step_Therapy_Type_Group_Desc_X If Step Therapy does not apply to this drug, then leave this field blank.	Step_Therapy_Type_Group_Step_1 = 4 (e Step 4 of 6) Step_Therapy_Type_Group_Step_2 = 1 (e. Step 1 of 3) Step_Therapy_Type_Group_Step_3 = 5 (e. Step 5 of 5)