DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Room 303-D
200 Independence Avenue, SW
Washington, DC 20201

FACT SHEET

DRAFT GUIDANCE -- CMS FORMULARY REVIEW FOR THE MEDICARE PRESCRIPTION DRUG BENEFIT

The Medicare Modernization Act's addition of a prescription drug benefit represents a landmark improvement in the health care coverage available to Medicare beneficiaries. The formulary review is part of CMS's broader review of the design of the plan and its benefits. For the final regulation CMS is considering policies to assure beneficiaries have access to covered drugs that are medically necessary, while enabling plans to design and manage their formularies to provide the most affordable benefit possible.

CMS will achieve this by approving formularies that give all Medicare beneficiaries access to the kinds of drug formularies already providing effective drug coverage to millions seniors and people with disabilities through existing drug plans, such as those covering federal employees, private sector retirees and "dual eligible" beneficiaries in state Medicaid programs. CMS will look to approve formularies and benefit management approaches that are currently working in these drug plans, and will use comparisons to widely-used national standards, guidelines, and existing formularies as checks on the comprehensiveness of these formularies. CMS believes beneficiaries can gain from the application of these widely used approaches to Medicare prescription drug benefit plans. CMS will support the use of USP model classes and categories for plans that choose to use them, though plans are not required to do so, and CMS oversight includes many other aspects of the drug benefit in addition to the classification system.

The MMA is designed to enable prescription drug plans to offer comprehensive drug coverage by providing flexibility. The goal, however, is not to save money at the expense of appropriate medical care. Plans would be expected to accommodate widely applied guidelines and support current treatment options for conditions such as asthma, diabetes, behavioral health and psychological disorders, lipid disorders, hypertension and HIV.

The CMS formulary review will follow four important principles:

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 non-discriminating, appropriate access.
2. Provide Access to Medically Necessary Drugs: We will require that drug plans provide access to medically necessary treatments for all and do not discriminate against any particular types of beneficiaries based on their expected drug costs.
3. Flexibility: CMS will allow plans to be flexible in their benefit designs to promote real beneficiary choice while protecting beneficiaries from discrimination.
4. Administrative Efficiency: CMS will set up a process to conduct effective reviews of plan offerings within a compressed period of time.

The process CMS intends to use for formulary review will focus on three areas:

- **Pharmacy and Therapeutics committees**, the forum for an evidence-based 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. The committee will have to be consistent with the pharmacy benefit management principles 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/), or the Academy of Managed Care Pharmacy (AMCP Principles of a Sound Drug Formulary System October 2000, www.amcp.org).
- **Formulary lists**, where CMS will look to best practices in existing drug benefits serving millions of seniors and people with disabilities to ensure access to medically necessary drugs. We expect that the kinds of formularies in widespread use today, which provide high-quality coverage to millions of Medicare beneficiaries, would receive a straightforward approval under this approach. We are considering a range of methods to evaluate formularies to check that they meet best practices. CMS will evaluate formulary classification systems as well as the actual list of drugs included in the formulary. Regardless of the classification system, CMS will review specific drugs in each category and class to ensure that the formulary offers a sufficient breadth of drugs necessary to treat all disease states in a non-discriminatory way. The law requires at least two drugs in each approved category and class, however, CMS may require more than two drugs per class in cases where additional drugs present unique and important therapeutic advantages in terms of safety and efficacy. We have identified examples of broad formularies that appear to successfully provide drug coverage to many beneficiaries today, and we seek comment on the use of these and other formularies as examples for our review process. These include commercial formularies such as those available in the Federal Employees Health Benefit Program (e.g.http://members.kaiserpermanente.org/kpweb/covereddrugs/entrypage.do, www.firsthealth.com/mhbp, or https://www.advancerx.com/advpcsrx_pmwroot/pmwroot/Formulary/00607/IndexForm.jsp?com=fep) and State Preferred Drug Lists (e.g. http://www.mass.gov/Eeohhs2/docs/masshealth/pharmacy/mh_druglist.pdf and http://www.fdhc.state.fl.us/Medicaid/Prescribed_Drug/pharm_thera/fmpdl.pdf).
- **Benefit management tools**, where CMS will compare plans' use of tools such as prior authorization to the way these tools are used in existing plans in order to make sure the tools are applied in a clinically appropriate and non-discriminatory fashion. We also will protect beneficiary rights in areas related to appeals and exceptions by incorporating appropriate appeals and exceptions standards in our final regulations and by reviewing processes that plans use to provide timely access.

The following paper, written in response to comments CMS received on the proposed rule for the new Medicare outpatient drug benefit, invites public comment. Final formulary guidelines will be published early in 2005.