BENEFICIARY PROTECTIONS

The new drug benefit will include similar rights and protections featured in other parts of Medicare, so all beneficiaries will have access to medically necessary treatments.

The Medicare Modernization Act (MMA) incorporates substantial beneficiary protections from traditional Medicare and from the Medicare+Choice program. It also creates new rights and protections that are specific to the drug benefit.

- Guaranteed issue – Prescription drug plans, and the Medicare Advantage plans, have to accept all eligible enrollees who reside in their service area, regardless of their age or health status.

- Uniform benefits and premiums – Except as provided for in law (with respect to the low-income subsidies), plans must provide all their enrollees with the same benefits and charge a community-rated premium.

- Formulary protections – Plans' formularies must include two drugs from every therapeutic category and class, with only a few exceptions. They must also develop the formulary with the help of a pharmacy and therapeutic committee that includes practicing pharmacists, physicians, and an expert in geriatric care. This committee will use the best scientific evidence on drugs' safety and efficacy and side effects to enhance quality while controlling costs.

- Grievance and appeals requirements – Plans will be required to have a grievance and appeals process that allows beneficiaries to challenge the formulary. Under such a challenge, called an exception, a non-formulary drug could be covered, or a non-preferred drug could be covered under the terms applicable for a preferred drug under certain conditions. We are proposing that plans have reasonable flexibility to design their exceptions criteria. As part of this process, the prescribing physician would have to determine that the preferred drug (or all the formulary drugs) either would not be as effective for the individual, or would have adverse effects for the individual, or both. Physicians and authorized representatives (such as a family member) can assist beneficiaries in challenging a plans' formulary or tiers, though, by law, only the enrollee or authorized representative can file an external appeal.

- Information – Plans must provide a wide range of information to beneficiaries, including how the formulary works, what the plan benefits are, and how the plan's medication therapy management program works. They must also provide, upon request, information on the grievance and appeals process and how the plans

have performed in this area.

- Customer service – Plans must respond to beneficiary questions in a timely manner, including responses through a toll-free telephone number and by placing information on the Internet. They must also provide beneficiaries with a clear, explanation of benefits, report detailing how much prescription drug spending they have had for the year, as well as how close they may be to the catastrophic coverage benefit.

- Pharmacy access – Plans must assemble broad networks of retail pharmacies to provide convenient access, no matter whether the beneficiary lives in an urban, suburban, or rural area.

- Cost management – Plans are required to have cost management programs that save beneficiaries money with tools such as generic and therapeutic substitution to more cost-effective therapies.

- Therapy management – Plans must have medication therapy management programs to help beneficiaries who have multiple, chronic conditions, use multiple drugs and expect to have high drug costs, make sure they are taking safe combinations of drugs and using the drugs properly.

- Generic drug information – Plans and pharmacists are required to inform the beneficiary if he or she could save money by using a generic drug instead of a more expensive brand name drug. Generic drugs are certified by the Food and Drug Administration as just as safe and effective as their brand name counterparts, yet they often cost just a fraction of the brand price.

- Privacy – Plans must maintain privacy and confidentiality of patient records.

- Collecting satisfaction data – Plans are also required to participate in consumer satisfaction surveys, which allow enrollees to rate their experience with plans. The ratings will be published in Medicare's comparative plan brochures and provide key information for beneficiaries to use when choosing plans.

Comments on the proposed regulations will be accepted until October 4, 2004. Comments should be submitted to the Centers for Medicare & Medicaid Services at www.cms.hhs.gov/regulations/ecomments