CMS Further Strengthens Beneficiary Protections in Part D To Ensure That All Beneficiaries Get Access to Medically Necessary Drugs

The new drug benefit will include rights and protections similar to those in other parts of Medicare, and Medicare's final rule incorporates additional rights and protections related to the drug benefit in response to public comments on the proposed rule. These rights and protections are intended to ensure beneficiaries have access to medically necessary treatments, and prevent discrimination in the drug benefit against beneficiaries with high drug costs.

Access to Medically Necessary Medications

CMS has taken a number steps to ensure that beneficiaries will receive clinically appropriate medications at the lowest possible cost. We will review every plan's formulary to make sure each plan provides beneficiaries with access to medically necessary drugs and does not discriminate against any particular type of beneficiary. CMS will use principles outlined in its guidance for plans to provide clarity in how it will review formularies to ensure such access and fair treatment for beneficiaries. CMS' review of plan formularies will be guided by best practices used by drug plans currently serving millions of seniors and people with disabilities.

Streamlined Coverage Determination (Exceptions) and Appeals Processes

CMS has incorporated substantial enrollee protections in the Part D exceptions and appeals processes which build on the processes used for the Medicare Advantage program and reflect additional considerations for prescription drugs. Attached at the end of this paper is a flow chart briefly summarizing the coverage determination (exceptions) and appeals processes to help protect beneficiary rights to new Medicare drug benefit.

Beneficiaries or their designated representatives can appeal the results of the coverage determination (exceptions) process. All drug plans are required to have a timely coverage determination process, and CMS will review each plan's coverage determination process to ensure that it provides a timely and fair opportunity to review coverage decisions. In response to comments received on the proposed rule, CMS has significantly shortened timeframes for plans to make coverage determinations and appeal decisions so that enrollees will quickly receive decisions about the medication that their doctors have ordered for them. Specifically, CMS has reduced the timeframe for making coverage determinations to be made from 14 days to no later less than 72 hours for standard requests or 24 hours for expedited requests. Likewise, CMS shortened most of the decision making timeframes for appeals. (We originally proposed a 7-day response time for standard appeals and 72 hours for expedited appeals). These shortened response times will ensure that enrollees can avoid paying out-of-pocket for their medications while they are awaiting a decision.

CMS believes that relevant physician expertise in a fair process for appeals decisions is essential. Therefore, CMS is requiring that the Independent Review Entity (IRE) base its decisions on medical appropriateness. If a plan bases its denial on a lack of medical necessity, the IRE must ensure its review is conducted by a physician with expertise in the field of medicine that pertains to the enrollees' request. In addition, CMS is requiring that network pharmacies and pharmacists provide enrollees with simple and easy-to-understand notices of their rights when they disagree with the information provided by their pharmacists. These notices will advise the enrollees of

their right to contact their plans to receive a formal coverage determination that may be appealed if unfavorable.

Adequate Notice of Formulary Changes

In order to provide appropriate continuity of care, with an opportunity for beneficiaries to transition their medicines smoothly and to retain access to needed treatments, CMS has taken steps to ensure that beneficiaries have adequate notice of formulary changes. Based on comments to the proposed rule, CMS has increased the amount of advance notice required for plans to notify their enrollees of any formulary or cost-sharing level changes that occur during the plan year, from 30 days to at least 60 days in advance of the effective date of change. As an additional beneficiary protection, if a plan fails to provide an enrollee with such notice, it must provide the enrollee with a 60-day supply of the drug and the notice of change when the enrollee requests a refill of the drug affected by the change. This notice is intended to provide beneficiaries with sufficient time to respond to any coverage changes, including arranging to continue coverage for any medically necessary treatments and filing exceptions and appeals requests if necessary.

Requirements to Ensure Up-to-Date, Comprehensive Drug Coverage: P&T Committees, Formulary Oversight and Oversight of Cost Management Tools

In order to facilitate a balanced formulary design process, CMS is requiring plans to have Pharmacy &Therapeutics (P&T) committees that include practicing pharmacists, physicians and experts in geriatric and disabled care. The P&T committees are required to follow a complete set of best practices, to ensure that they use the best medical evidence on drugs' safety, efficacy and side effects to enhance quality while controlling costs. For example: at least one of the P&T committee members must be independent and free of conflict from the interests of the plan; P&T committee members must represent various clinical specialties that adequately represent the needs of plan beneficiaries; and 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.

Once a formulary is submitted to CMS by a plan, CMS will conduct a thorough review of the formulary. Our review will incorporate best practices from the private sector, Medicaid, and Federal Employee Health Benefits Program (FEHBP) 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. CMS will publish its finalized formulary guidelines so that plans will be aware of the in-depth review CMS intends to conduct for each formulary submitted. Within those guidelines, CMS has developed a series of checks it will use to confirm that plan formularies will be providing the kind of effective, non-discriminatory access available in drug benefit plans today. For example, not only will CMS review the formularies' categories and classes, but will also review and approve drug lists that are consistent with "best practice" formularies in widespread use today.

Also, as a part of its formulary guidelines, CMS will provide information on its review plan benefit management tools (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. CMS will look to current industry standards as

well as appropriate guidelines that might be found from expert organizations such as the National Committee on Quality Assurance and the National Association of Insurance Commissioners and to the use of such standards in existing drug plans that are widely used by seniors and people with disabilities. Again, CMS will focus on ensuring that all of these plan benefit management tools reflect current best practices utilized in the private sector, Medicaid and FEHBP plans.

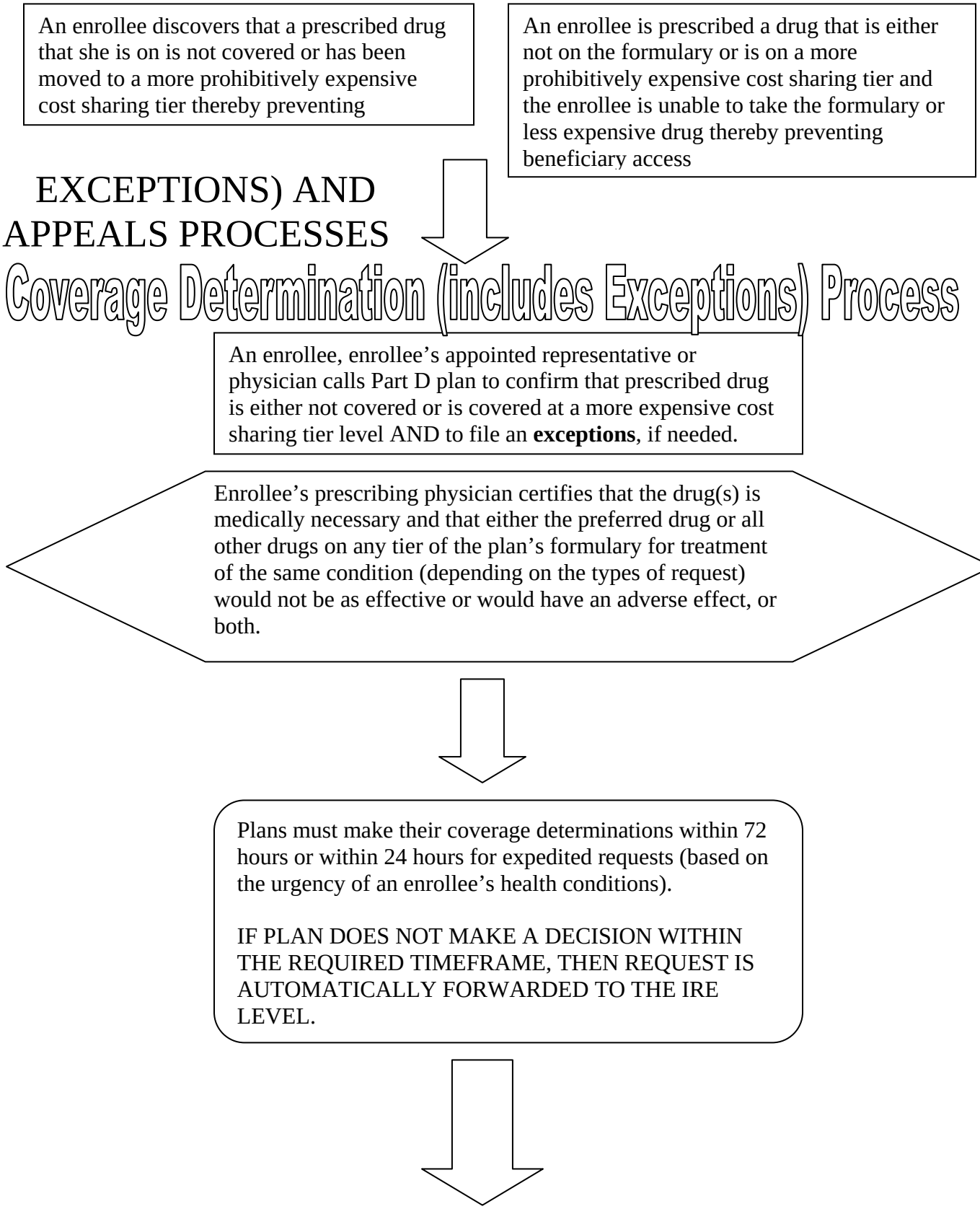
Strong Financial Incentives for Access to Needed Medicines for Beneficiaries with Costly Illnesses

The new Medicare prescription drug program includes strong financial incentives to conveniently provide an appropriate range of drugs for all types of beneficiaries, including the Medicare/Medicaid "dual eligible" population and beneficiaries with costly chronic illnesses. Full-benefit dual eligible beneficiaries will receive generous subsidies for their drug costs. Institutionalized, full-benefit dual eligible individuals pay no cost-sharing whatsoever. All beneficiaries will get protection against very high drug costs. The Medicare drug benefit will include a set of financial incentives to help ensure that these beneficiaries get the treatments they need:

- Medicare will adjust its payments to drug plans based on the expected costs of the beneficiaries who actually enroll, with higher payments based on beneficiaries' demographic characteristics, their chronic diseases, whether they qualify for the low-income subsidy, and whether they reside in a nursing home.
- Medicare will cover 80 percent of the costs of very high drug expenditures.
- Medicare will reimburse plans for most plan costs if expenses exceed expected levels by more than 2.5 percent (and similarly, Medicare will retain most of the extra revenues if plans have actual expenses that are significantly lower than expected).

Because of risk adjustment of the Medicare subsidies and the reinsurance and risk corridor payments, Medicare payments will be concentrated on beneficiaries with high drug costs, or little income to pay for their drug costs.

COVERAGE DETERMINATION (INCLUDES EXCEPTIONS) AND APPEALS PROCESSES



Appeals Process

Level One

If a plan makes a decision that is unfavorable to the enrollee, the enrollee or appointed representative may file a request for a redetermination.

Level Two

If a plan makes a redetermination that is unfavorable to the enrollee, the enrollee or appointed representative may request a reconsideration by **an Independent Review Entity (IRE),** which is a CMS contractor that reviews determinations made by a plan.

Level Three

If the IRE's reconsideration is unfavorable, an enrollee may request a hearing with an **Administrative Law Judge (ALJ)** if the amount in controversy requirement is satisfied.

Level Four

If the ALJ's decision is unfavorable, the enrollee may appeal to the **Medicare Appeals Council (MAC)**, an entity within the Department of Health and Human Services that reviews ALJ's decisions.

Level Five

If the MAC's decision is unfavorable, the enrollee may appeal to a **Federal district court**, if the amount in controversy requirement is satisfied.