



December 30, 2004

Centers for Medicare and Medicaid Services

The Medicare Consumers Working Group, a coalition of health care and consumer organizations, submits these comments on CMS' draft guidance – *CMS Formulary Review for the Medicare Prescription Drug Benefit*. Together, our organizations represent a wide range of Medicare beneficiaries and a cross-section of interests and expertise: consumer and Medicare beneficiary advocacy organizations; organizations addressing the needs of individuals with specific diseases or disabilities; legal services; unions; and research and policy institutes.

While we have several recommendations that we believe are critically necessary to build on your proposed review process, we are generally supportive of the approach that CMS proposes to take with respect to reviewing Part D plan benefit structures and formularies. We are also pleased to see that CMS recognizes the need to review Part D plan formularies to ensure that they do not discriminate or substantially discourage enrollment by certain groups of Medicare beneficiaries. We support the identification of three areas of focus: pharmacy and therapeutics (P&T) committees, formulary lists, and benefit management tools as among the most critical areas for your review. We are also pleased that CMS is viewing the statutory requirement of two drugs per class as a floor, and not an absolute standard. We are encouraged that CMS recognizes the need to look at each plan's use of cost management tools. We are also pleased that CMS intends to show deference to widely accepted clinical practice guidelines. Making certain that the appeals process works effectively for beneficiaries is critically important, and we are encouraged by CMS's statements that they will require standardized reporting by plans on denials, reconsiderations and appeals and exceptions processing and will integrate this data into CMS management and oversight activities.

Although the enactment of the MMA was predicated on the idea that market competition will yield efficiencies in the delivery of prescription drug benefits, we remain skeptical of many of the rationales put forth. Moreover, it is our belief that if the MMA is implemented successfully, competition and beneficiary choice will be driven by factors such as efficient administration of plan benefits, and will not be driven primarily by differences in plan formularies. Indeed, successful implementation of the MMA requires all plans to have similar formularies—and

ones that meet the needs of all Medicare beneficiaries, including persons with complex conditions, persons with very extensive needs, persons whose prescription drug needs change frequently, low-income persons, and others. For this outcome to be achieved, CMS must use its regulatory authority and staff resources to focus cost-management activities in areas where there is a consensus among relevant medical professionals based on a thorough review of clinical evidence relevant to the Medicare population (including non-elderly individuals and low-income individuals) that access restrictions are appropriate. Moreover, we believe that there are both successes and failures of state efforts to manage the pharmacy benefit in Medicaid that should inform your review process. We believe that Part D plans should not seek to manage the pharmacy benefit through restrictions and formulary limitations in every drug class or nearly every drug class. Unless proven otherwise, the presumption should be that each drug in a class is unique and not interchangeable. Where drugs are not equivalent, all drugs should be on-formulary drugs and the cost of the drug should not be a factor in establishing cost-sharing levels—especially since the MMA’s cost-sharing structure (which is based on a percentage of the drug’s cost) already means that more expensive drugs will have higher cost-sharing.

For classes of drugs for which there is a broad consensus supported by clinical evidence that drugs are clinically equivalent, plans should be permitted to limit access or use cost-sharing (with safeguards such as limits on the level of cost-sharing and the number of cost-sharing tiers permitted) to restrict access to the federal minimum of two drugs per class. Through regulations and the formulary review process, CMS should ensure that plans start cautiously in applying formulary restrictions to a narrow range of drug classes for which the evidence of clinical equivalency is the strongest. For positive examples of how states have done this, we encourage CMS to consider the experience of the Medicaid program in Kansas. Other states have been less successful in managing the pharmacy benefit without inappropriately hindering access to medically necessary drugs. For example, Florida’s experience—and reliance on cost above clinical factors—is an example of a state program that should not be emulated in the Part D program. Please note that we were troubled to see the reference to Florida in the draft guidance for this reason. We also believe that the early experience with a preferred drug list (PDL) in Michigan illustrates the risks and harm that could come about if CMS does not ensure that Part D plans establish benefit structures and formulary policies based on clinical evidence. We note that Michigan has subsequently rolled back many of its policies. In particular, coverage of mental health drugs has become much less restrictive than when the program was initially implemented. We also believe that the state experience highlights the need for transparency and buy-in from all stakeholders. Again, the early experience with Michigan’s PDL illustrates what CMS should not permit Part D plans to do—and we note that the state has subsequently adopted a much more constructive relationship with beneficiary representatives and other stakeholders.

We must emphasize that many consumer organizations very reluctantly acknowledge that any formulary limitations are acceptable. In our comments, we would like to explicitly state that we believe that a reliance on clinical evidence must necessarily preclude Part D plans from imposing formulary limitations on a broad range of classes of drugs including antiretrovirals used in the treatment of HIV/AIDS, mental health drugs, anticonvulsants, and others. We also must emphasize that even in cases where drugs within a class have been determined to be clinically equivalent, CMS must ensure that individual's are readily able to gain affordable access to specific drugs based on factors such as normal variations in responsiveness to prescription drugs and consideration of factors such as ability to adhere to treatment. Finally, CMS must ensure access to off-label drugs.

### **Critical Issues**

Within the framework identified by the proposed guidance, the following are critical issues that we believe must be addressed.

- 1 Defining a “best practice” and “medical necessity”**
- 2 Determining which sector is the most appropriate benchmark for the Medicare population**
- 3 Access to newly approved pharmaceuticals**
- 4 Ensuring that P&T Committees function effectively**
- 5 Role of clinical evidence and cost in making formulary decisions**
- 6 Appropriate use of benefit management tools**
- 7 Burden on beneficiaries, physicians and pharmacists**
- 8 Non-discrimination in the use of cost-sharing tiers**
- 9 Review of appeals and exceptions procedures**
- 10 Issues related to residents of long-term care facilities**

### **Defining a “best practice” and “medical necessity”**

We believe that it is essential that CMS define what is a “best practice.” In particular, we are concerned that just because one health plan/insurer in the private sector or one Medicaid program adopts a policy, does not mean that this policy is a best practice for the purposes of CMS’ review of a Part D plan’s benefit structure or formulary policy. We believe that “best practices” are those policies and practices that have gained broad acceptance from a broad range of stakeholders—and this must always include broad acceptance by the affected beneficiary population and acceptance by providers with the most appropriate clinical expertise. Best practices should also be defined as those policies that result in the best outcomes for consumers in terms of the fewest complications from drug therapies, the fewest and least severe side effects, the lowest rates of hospitalization, and when appropriate, the lowest relapse rates for individuals unable to adhere to a course of therapy. CMS should establish a process for continually reviewing best-practices as well as evaluating the experience of Part

D plans to determine how their plan review and evaluation processes should be changed as new therapies become available, additional information is gathered on current therapies, and medical practice changes. At least once per year, CMS should update its guidance accordingly. The final CMS guidance should specifically list the best practices CMS will use as benchmarks in assessing proposed formularies and plan benefit structures.

Population differences may influence what is a best practice; the best practice for persons with employer-sponsored health coverage provided in the private sector may differ from a sicker, poorer, older, and more disabled population served by Medicare. Moreover, an evaluation of clinical evidence must consider characteristics of the sample population studied. For example, clinical evidence examining the efficaciousness of a prescription drug among healthy, non-elderly men should not be considered directly applicable to elderly women or anyone with multiple illnesses. In the discussion of drug list reviews, the draft guidance talks about one benchmark being the availability of commonly prescribed drugs, defined as the top 25-50 drugs for the Medicare population in terms of cost and utilization. With regard to the Medicare discount card, the Medicare website now indicates how many of the top 100 drugs are available for each card. It turns out, however, that the definition of top 100 is based on those drugs which are most used (in terms of total dollar value) by the over-65 population, thus not including use by people with disabilities under age 65.

Additionally, other terms should be defined by CMS. It is unclear, for instance, what test CMS will use to assure that beneficiaries have access to all “medically necessary” drugs, including those not on the formularies of the private drug plans and Medicare Advantage plans that will be offering the new Medicare drug benefit. CMS should not just rely on the plans’ definitions of “medical necessity” given the financial incentives of these private plans to limit access to off-formulary medications as much as possible. By leaving the medical necessity standard to each plan, CMS will develop a situation in which one PDP in an area may determine a drug to be medically necessary in a given situation, while a second plan serving the same area will come to a different conclusion. Such a result is inherently discriminatory and inequitable. Further, doctors and other prescribers will be unduly burdened by having to remember and comply with different standards for the various Medicare Part D plans in which their patients are enrolled. We know from experience as beneficiary advocates that when doctors are overburdened, they are less willing and able to provide the assistance that beneficiaries need.

We recommend that CMS establish a federal definition of medical necessity along the lines of the medical necessity standard for Medicare Parts A and B. That standard provides coverage for all services except those that are not “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” We would further recommend that the definition clearly include as medically necessary

medications needed to maintain or to improve functioning, or to prevent deterioration of the underlying medical condition. In the Medicaid context, Pennsylvania's definition of medical necessity also provides an important basis for a definition of medical necessity in the context of the Part D program.

Pennsylvania defines a medical necessary service as, "a service or benefit (that will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability. The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age."

### **Determining which sector is the most appropriate benchmark for the Medicare population**

While we agree that formularies used by other insurers may form a benchmark or basis for comparison with formularies offered by Medicare Part D plans, we urge CMS to recognize that the Medicare population differs significantly from the populations served by most other plans. Overall, Medicare beneficiaries are older and sicker, have more chronic conditions, and rely on more prescriptions than enrollees in other insurance programs. For example, the average age of those insured by FEHBP, 62, is younger than the age of eligibility of the majority of Medicare beneficiaries. Drugs included on some of these formulary lists may not be as effective as others in the same category or class for older people, may not interact well with other common drugs used by elders, or may be contra-indicated for older people. Thus, we ask CMS to pay particular attention to plans, including state Medicaid programs, county hospitals, and long-term care facilities, that serve individuals who are of similar age and health status as Medicare beneficiaries. We request CMS to consider as well the format in which drugs are available and the packaging, as these are also considerations for some Medicare beneficiaries.

### **Access to newly approved pharmaceuticals**

We are pleased that CMS acknowledges the need for plans to consider providing coverage for new chemical entities, although the draft guidance is insufficient. In particular, persons with life-threatening conditions and persons who have failed to successfully treat a chronic condition with existing prescription medications should have immediate access to new treatments once they receive approval by the Food and Drug Administration. The draft guidance states that a best practice is to require P&T Committees to review each new chemical entity within 90 days of its release onto the market, or a clinical justification must be provided if this timeframe is not met. We believe that this length of time is too long, and does not take into consideration unique characteristics of the Medicare population. Millions of Medicare beneficiaries are individuals who qualify for coverage

because they have met a strict standard for permanent and severe disability—and these individuals are generally not well represented in the private insurance market. Therefore, a private insurance standard would not meet the needs of the Medicare population. Many Medicare beneficiaries have life-threatening or chronic conditions for which there is no effective treatment. When new chemical agents are approved, these individuals need immediate access to all new treatments.

Consistent with our previous comments on the proposed Part D regulations, we strongly recommend that CMS declare through regulations that certain groups are special populations who will have access to open formularies or formularies which show greater deference to the treating physician in determining coverage of specific pharmaceuticals. These individuals must also have unhindered access to all medically necessary newly approved drugs and chemical agents as soon as they receive FDA-approval. We also believe that the default position should be that newly approved chemical agents are unique and not interchangeable—and should have immediate access to these drugs. For drugs in classes which have been determined to be clinically equivalent, Part D plans could be given 60 days to determine clinical equivalence. If a plan does not act within 60 days, the drug should be covered at the standard cost-sharing level.

### **Ensuring that P&T Committees function effectively**

We concur that the P&T Committee is vital and that P&T operations should ensure that the benefit is clinically sound and nondiscriminatory. We do, however, have some concerns with the guidance regarding P&T structure. Specifically, the requirements listed do not adequately ensure that determinations will meet the desired goal of being clinically sound, unbiased, and nondiscriminatory.

- 1 P&T Requirement. The draft guidance, as written, seems to anticipate that all plans will have formularies and thus have to have a P&T committee under the MMA requirements. However, while unlikely, it is possible that a plan might not have a formulary. All Part D plans—with or without formularies—should be required to have a P&T Committee to conduct best practice reviews, evaluate physician prescribing, etc. Therefore, we recommend that the Guidance state that all plans should have a P&T Committee that meets the outlined membership and conflict of interest requirements and has responsibilities including (but not limited to) evaluating beneficiary drug use patterns, compliance reviews, establishing and monitoring drug screen processes to reduce adverse events.

Further, the Guidance should outline the goals and objectives of the P&T Committee to include a charge for P&T committees to “ensure that the interests of enrollees, taking into account the unique needs and co-morbidities commonly associated with aging populations and people with

disabilities served by Medicare, are protected by all formulary and benefit design decisions made by the Part D plan” and that P&T decisions be made with the goal of ensuring “adequate access for the most clinically efficacious drugs in the preferred tier for all classes of covered drugs.” Plans should be required to have sanctions for P&T Committee members who act in gross violation of this charge.

- 2 Composition, P&T Committee. The elderly and individuals with disabilities respond very differently to medications from the general population. Elderly patients are particularly vulnerable to drug-related problems and have a high rate of drug-drug interactions. This is because of the frequency with which they take multiple medications, as well as age related changes in pharmacokinetics, and frequent compliance issues (Merck Manual of Geriatrics). Because these plans will be serving the elderly and individuals with disabilities, we urge that the Guidance incorporate P&T committee membership requirements that will better ensure that the unique needs of the Medicare population are adequately addressed:
  - That each P&T committee have at least one physician and one pharmacist with expertise and experience in the care of the elderly and one physician and one pharmacist expertise and experience in the care of people with disabilities.
  - That each P&T committee also include one member that is an independent long term care pharmacist (can be overlap with experts in specific clinical areas).
  - P&T Committees will not be able to have adequate expertise from all clinical areas. The guidance should state that P&T Committees must have contractual relationships with a wide variety of specialists/experts in specific areas of practice who can be used as consultants. Contracted specialists should include individuals expert in nephrology, oncology, neurology, orthopedics, rheumatology, pulmonology, cardiology, infectious diseases, mental illness, obstetrics/gynecology, and rare disorders. The diseases and disease states treated by those medical specialties are common among Medicare beneficiaries; requiring that P&T Committees have formalized arrangement to draw on the appropriate clinical expertise as needed will support CMS’s stated goal of clinically sound P&T determinations.
- 3 Conflict of Interest. The Guidance requires only that one pharmacist and one physician on the P&T Committee be independent and free of conflict with respect to the sponsor and plan. This is insufficient to ensure that the P&T Committee is unbiased. At the least, the guidance should require that a majority of members be independent and free of conflict with respect to the sponsor, the plan, and pharmaceutical manufacturers. This will promote unbiased review; the current requirement in the Guidance is

- inadequate to meet that goal. We also urge that the conflict of interest statement the Guidance says P&T committee members should sign be available to the public.
- 4 Meeting Administration. We have several areas where we recommend additional administrative provisions to ensure that P&T Committee decisions are timely and unbiased.
- We support the requirement for monthly meetings and for written documentation. However, there may be times when decisions are required between meetings. The Guidance should require each P&T Committee to have procedures for determinations and decision making between scheduled sessions.
  - Part D plan P&T Committees are making significant decisions regarding administration of Medicare's drug benefit and beneficiaries' access to therapies. The Guidance should require that P&T Committee meetings be open to the public. Again, we would like to emphasize our view that a critical determinant of whether the P&T committee process works effectively is the extent to which it is open and transparent, and engenders trust from all stakeholders. We encourage you to contact the Medicaid programs previously mentioned to learn of their experience in this regard.
- 5 Formulary Management/Formulary Exceptions. We are very concerned about beneficiaries' access when the appropriate drug is not on formulary.
- We are particularly concerned about situations where a beneficiary has tried and failed on a "preferred drug." P&T Committees should be required to develop procedures for plans to accept prior medical records demonstrating that a preferred drug has failed. To require beneficiaries to again try and fail on the same drug as tried before in order to gain a formulary exception is potentially detrimental to the beneficiaries' health and adds unnecessary costs to the medical system. This is also an important issue as beneficiaries switch enrollment between plans from year to year.
  - In addition, in the bullet relating to Formulary Exceptions, we urge CMS to require a 'grandfathering' of beneficiaries, including dual eligibles, who at the time of enrollment have been stabilized on a treatment regimen and not subject them to potentially harmful changes in prescriptions at the time of enrollment in the new program—regardless of whether they have failed on other therapies. If this is not done, we predict major problems in the public's acceptance of the new program in the spring of 2006.

- In the discussion of “Formulary Management”, we also urge that P&T committees must review the appropriateness of tiering. Tier assignment may be far more important in how plans operate their formularies than the simpler question of whether or not a drug is on the formulary.
- 6 Binding Determination. We also recommend that the determinations of a predominately independent P&T Committee be binding on the plan.

### **Role of clinical evidence and cost in making formulary decisions**

While we understand that for classes of drugs that have been determined to be clinically equivalent cost will be an important consideration in establishing formulary policies, we believe it is critically important to separate the review of clinical evidence conducted by medical professionals on the P&T committee from consideration of cost by the Part D plan. Again, we believe that the experience of state Medicaid programs is instructive. For the P&T committee review to be accepted by plan enrollees, providers, and pharmaceutical manufacturers, it is important to ensure that the P&T committee review process is focused exclusively on a review of drug classes for clinical equivalence based on a review of clinical evidence and clinical experience. To achieve this, we recommend that CMS prohibit plan employees from serving as voting members of the P&T committee (although they can provide staff support), and we recommend that P&T committee members not be given cost information. We believe that the P&T committee should make a determination of whether a class of drugs is clinically equivalent. Only after such a determination has been made should plan employees become engaged in establishing formulary policies on the basis of cost. We believe that state Medicaid experience in Virginia, Kansas, and Washington can be instructive to CMS’ efforts.

We also take issue with the statement in the draft guidance that, “The P&T committee will also be expected to analyze and recommend, where appropriate, regional variations of national best practices.” As a national program, CMS must ensure a uniform and non-discriminatory application of program rules and policies. We do not believe there is ever a justification for regional variation of best practices when these practices are established based on clinical evidence.

### **Appropriate use of benefit management tools**

We strongly support CMS’ statement in the draft guidance that they will review each plan’s use of drug utilization review tools and techniques, including concurrent review and prospective and/or retrospective utilization review, to ensure appropriate access to medically necessary therapies and guard against inappropriate or dangerous utilization.

We strongly recommend that CMS prohibit plans from engaging in therapeutic

substitution (without the voluntary consent of the treating provider) and placing limits on the amount, duration, and scope of coverage for covered Part D drugs through limits on the frequency of dispensing, maximum daily dosage, or limits on the number of prescriptions filled. Prohibiting such limits would be consistent with comments from Dr. Mark McClellan during his confirmation hearing before the Senate Finance Committee related to his current position as CMS Administrator. In response to Senator Baucus' question number 27, Dr. McClellan stated that, "beneficiaries who elect to enroll in this new open-ended drug benefit will have no limits on the number of prescriptions filled, no limits on the maximum daily dosage, and no limits on the frequency of dispensing of a drug."

We are also concerned about the application of prior authorization and urge CMS to look at what has and has not worked in the Medicaid program as a guideline for setting standards for prior authorization programs (e.g., use of "dispense as written" provisions, time frame for determinations, access to therapy in emergency situations). We urge that, when prior authorization is imposed, if the prior authorization process has not been completed within 24 hours of the time that a prescription was first presented at a pharmacy, plans be required to dispense a temporary supply of the prescribed drug pending the completion of the prior authorization process, including any time needed to receive an exception process and appeal decision. The final rule must also provide for exigent circumstances when an emergency temporary supply of a prescription drug must be dispensed immediately, without allowing for a 24 hour prior authorization period. Plans should be required to report on appeals (number of appeals, determinations, time frame for decisions); performance on appeals is a critical measure of overall plan performance and beneficiary access.

In assessing plans' use of benefit management tools, the draft guidance states that CMS will compare the use of these tools (e.g., prior authorization, step therapy, generic substitution) in the Medicare drug plans and Medicare Advantage plans to the use of these techniques in existing plans (private sector, Medicaid, FEHBP) to ensure non-discrimination. Most state Medicaid programs have highly tailored their use of prior authorization and fail first policies. It is believed that most drugs dispensed by most Medicaid programs do not require prior authorization. Further, classes of drugs for the treatment of mental illness, HIV/AIDS, drugs with a narrow therapeutic index, and others are commonly excluded from prior authorization. States also employ fail-first policies very selectively. Indeed, a review of state use of fail-first policies suggests that this policy tool is generally used only with drug classes for which there is strong evidence of clinical equivalence, and states generally do not use fail-first policies broadly across large numbers of drug classes.

We are very pleased that CMS will review utilization management tools as well as utilization review procedures and appeals, exceptions and grievance processes, as part of the effort to protect beneficiaries against discrimination.

Utilization management tools, if applied too stringently, work as barriers to receipt of medically necessary medications. Although utilization review procedures, including appeals processes, are supposed to help overcome these barriers, they themselves create additional barriers to receipt of medically necessary care when beneficiaries and doctors lack information about the processes and the processes are too complex. We suggest the following to ensure that the interests of beneficiaries are protected:

1. The utilization management and utilization review processes must be transparent and readily available to beneficiaries, doctors, and other providers. Information should be available in clear, plain language in written form for beneficiaries and on the Internet for providers and beneficiaries with Internet access.
2. Plans should not be allowed to have more than 3 tiers for cost-sharing; otherwise, the plan structure becomes too complicated for beneficiaries and providers. The descriptions of the tiers, including why co-payments for some brand name drugs are higher than for other brand name drugs, should be clear and available in plan literature. A tier that requires cost-sharing of more than 40% should be considered discriminatory per se.
3. Special consideration needs to be given to individuals who are transitioning to a Medicare Part D plan from another insurance source, or from one Medicare Part D plan to another. Individuals who require a more costly or non-formulary drug and who have already gone through a step therapy or fail first system should automatically be provided access to the medically necessary drug without having to go through the exception process. Individuals transitioning from Medicaid to Medicare on January 1, 2006 should be offered a "hold harmless" option in which they may continue on the drug on their Medicaid formulary with a doctor's prescription for up to six months to avoid a situation in which they are without required medicine. Failure to provide protection in transition situations may jeopardize the health of vulnerable individuals.
4. Prior authorization processes, if utilized, must be brief and easy to use. Doctors should be able to call the plan and get a decision immediately or within 24 hours. If the plan requires forms, the forms and their instructions for use should be simple. For example, according to beneficiary advocates, the 20-page explanation of the Missouri Medicaid prior authorization process and the need to complete FDA Form 3500 act as barriers to use of the process.
5. All drugs utilized in the treatment of diabetes, Alzheimer's disease, clotting disorders, HIV/AIDS, cancer, seizure disorders, transplant rejection, nausea in cancer patients, and mental illness should be included in formularies and on a tier that makes the drugs affordable.

6. The exception process must also be expedited. In most insurance situations, it is the doctor, and not the patient, who requests the exception. The pharmacy should contact the doctor in real time as soon as the pharmacy determines that a prescription is not on the formulary, and provide the beneficiary with a clear, easy to understand written explanation of why the prescription is not being filled and how the exception process works. The plans should be required to have a special hotline, available 24 hours a day, 7 days a week, for doctors to utilize to seek an exception. In addition, plans should be required to cover a 72-hour supply of the medication, pending the resolution of the exception.

### **Burden on beneficiaries, physicians and pharmacists**

In addition to reviewing plan decisions regarding which drug classes are subject to formulary limitations, and which drugs will receive preferential treatment through the use of tiered cost-sharing, it is important for CMS to evaluate the burden imposed on beneficiaries, physicians, and pharmacists who must navigate a plan's procedures for requesting prior authorization, an exception to standard formulary policies, or other aspects of a plan's treatment authorization system. We also believe that beneficiaries, physicians, and pharmacists will have limited time and other resources available for negotiating the treatment/payment authorization system. Therefore, CMS should encourage plans to selectively target the use of cost management tools, such as prior authorization, to those classes of drugs that are clinically equivalent and which have the greatest potential to contribute to overall cost-savings. Plans should be discouraged from establishing policies that rely on the indiscriminate use of prior authorization, fail first and other policies, as this could be unacceptably burdensome on beneficiaries, physicians, and pharmacists and could impede access to medically necessary drugs.

### **Non-discrimination in the use of cost-sharing tiers**

We are heartened by statements in the draft guidance indicating that CMS will review the tier placement and cost-sharing requirements of plans to ensure that they do not discourage enrollment by particular groups. We agree that just including a drug on a formulary may not be adequate to assure non-discrimination and urge CMS to closely review tier placement. CMS states that best practices in existing formularies and Medicaid PDLs only put drugs on higher co-pay tiers if a therapeutically equivalent drug is in a more "preferable" position. However, this practice may not ensure adequate access to mental health medications, anti-seizure medications and other drugs, in light of their non-interchangeability.

### **Review of appeals and exceptions procedures**

The draft guidance states that CMS will protect beneficiary rights relating to appeals and exceptions through standards in the final regulations regarding the Medicare drug benefit and by reviewing processes plans use to provide timely access to these avenues for challenging coverage decisions. CMS should regularly review how these processes play out and should establish triggers for special review if plan data submitted to CMS indicate high numbers of exceptions and appeals being filed by enrollees. These triggers for review must not be tied to high numbers of utilization management decisions being overturned because, at least under the appeals processes outlined in the proposed regulations, it will take a long time and many levels of review before beneficiaries will receive truly independent review of their cases.

We are heartened by CMS's statement that the final rule for the Medicare drug benefit will reflect best practices regarding timeframes for exceptions and appeals and that they are developing notice requirements to ensure beneficiaries understand their rights. We expressed strong concerns in our comments on the proposed rule that the grievance and appeals processes as outlined in the proposed regulations were overly complex, drawn-out, and inaccessible to beneficiaries.

We strongly support CMS's statements that they will require standardized reporting by plans on denials, reconsiderations and appeals and exceptions processing and will integrate this data into CMS oversight. CMS says this will assure plans make appropriate use of the data such as addressing excessive rates of overturned utilization management decisions. But CMS should not just rely on plans to do the right thing with this data. CMS should review it closely to identify plans with high numbers of exceptions requests and appeals and require those plans to modify their formularies and benefit management techniques to ensure their enrollees are receiving medications they need.

### **Issues related to residents of long-term care facilities**

In the last several months, there has been more and more discussion of the intense problems these formulary issues will have for those in long-term care facilities, including assisted living. The discussions point to absolute chaos in the delivery of drugs in the nation's skilled nursing facilities (SNFs) beginning on January 1, 2006. We urge a major, immediate review of the LTC situation. The LTC/SNF confusion is so severe that we urge CMS to hold special listening forums on the issue as soon as possible.

In conclusion, we appreciate the challenges facing CMS in establishing the Part D program, creating a formulary and benefit structure review process, and keeping abreast of changing conditions in the Part D program on an ongoing

basis. The review described in this draft guidance is the minimal type of review necessary. However, these activities will place enormous and highly technical demands on CMS and will require highly paid, specialized staffs. We are concerned about the resources available to CMS to adequately carry out these key functions, especially with the expiration of the \$1 billion in start-up monies just prior to the start of the new benefit. Many organizations have been supportive of increased and more predictable resources for CMS, and we would appreciate an estimate of the staff needs and cost of implementing these reviews so that we may be supportive. We hope to continue to support your efforts to implement the MMA. We encourage you to contact our organizations as you work through the multitude of activities necessary to establish a Medicare prescription drug benefit. Should you have questions about any of the comments here, or if you would like additional information, please contact Jeffrey S. Crowley, Health Policy Institute, Georgetown University (202.687.0652 or [jsc26@georgetown.edu](mailto:jsc26@georgetown.edu)).

These comments are respectfully submitted by the following organizations:

AIDS Action, Baltimore, Inc.  
AIDS Action, Washington, D.C.  
AIDS Foundation of Chicago  
The AIDS Institute  
AIDS Medicare Coalition Project  
American Academy of HIV Medicine  
American Association of People with Disabilities  
Association of University Centers on Disabilities (AUCD)  
Arizona Center for Disability Law  
Bazelon Center for Mental Health Law  
California Health Advocates  
California AIDS/HIV Health Alternatives - North Hollywood  
California F.O.U.N.D. - Los Angeles  
California Recovery Options - Los Angeles, California  
Center for Medicare Advocacy, Inc.  
Disability Law Project of Vermont Legal Aid  
Easter Seals  
Epilepsy Foundation  
Families U.S.A.  
Gay Men's Health Crisis  
HIV Medicine Association  
Lutheran Services in America  
Medicare Advocacy Project, Greater Boston Legal Services, on Behalf of Its  
Eligible Clients  
Medicare Advocacy Project, Vermont Legal Aid  
Medicare Rights Center  
National Alliance of State and Territorial AIDS Directors

National Association of County Behavioral Health and Developmental Disability  
Directors

National Association of Councils on Developmental Disabilities

National Council on Independent Living (NCIL)

National Health Law Program

National Mental Health Association

National Multiple Sclerosis Society

New Mexico Poz Coalition

Senior Citizens' Law Office, Albuquerque, New Mexico

Spina Bifida Association of America

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