May, 14 2010

Department of Health and Human Services
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted Via Email: partdbenefitimpl@cms.hhs.gov

RE: "Coverage Gap Discount Program"

To whom it may concern:

The undersigned organizations appreciate the opportunity to comment on the Coverage Gap Discount Program guidance. Please see our comments below. We look forward to working with you on this and other matters in the future. Should you have any questions or require additional information please contact Vicki Gottlich of the Center for Medicare Advocacy at 202-293-5760 or vgottlich@medicareadvocacy.org or Ilene Stein of the Medicare Rights Center at 202-637-0961 ext. 5.

Sincerely,

Center for Medicare Advocacy
Medicare Rights Center

Comments on Medicare Coverage Gap Discount Program

General - CMS should provide consumer friendly materials that explain the discount program and how it applies to brand name verses generic drugs. It is important that consumers are reminded of the guidelines of the program and when and how it applies to different populations and drugs frequently.

In addition, there is no price protection in the law that prevents manufacturers from dramatically increasing prices. If a drug price increases, we ask that CMS require plans in a timely manner to send notice to affected consumers that the price of the drug has changed so if it is no longer affordable, the consumer has the ability to work with his or her prescriber to transition to alternative drug.

§30 - Point of sale discounts: We appreciate that the discount will be provided to consumers at the point of sale. We ask, however, that consumers be provided with individualized notices at the point of sale each time they fill a prescription that explains the amount they are paying for prescriptions with each party's cost responsibility outlined and the process for requesting a coverage determination.

It is important for consumers to be provided an explanation of how the cost is calculated, i.e., the part that is attributable to the actual price of the drug and the part that is attributable to the dispensing fee. Consumers are expecting to pay 50% of the cost of the drug. They are not aware that the law allows the plan to add any applicable dispensing fee to half the negotiated drug price when determining their share of the cost. Providing consumers with this information at the pharmacy will eliminate confusion and avoid unnecessary complaints to the plan sponsor.

At a minimum, the required notice provided to consumers each time they fill a prescription should be amended to include information on a consumer's right and process to request a coverage determination regarding the availability and amount of the gap discount. However, in all cases if a plan denies a drug request, it is important that the consumer at the point of sale understand the basis for the denial and how to appeal the denial in order to avoid unintended future inefficiencies in the calculation of consumer and plan cost responsibility. Providing this information to consumers immediately will allow them to start the appeals process in the most expedient timeframe possible.

§30.6 – Explanation of benefits: The explanation of benefits (EOB) should include a statement that consumers have the right to ask for a coverage determination; similar to the statement on the Medicare Summary Notice (MSN) that describes appeal rights under Parts A and B. If the explanation of the cost is not provided at the pharmacy, we ask that it be included in the EOB. As previously stated, providing consumers with information about the determination process will help facilitate timely challenges and claims processing, allowing for a more accurate computation of individual and plans costs. Also, this serves a more overarching goal of educating consumers about their rights and helping them access medically necessary prescriptions.

§50.1 – General Rule: More guidance is needed concerning the manufacturer agreements. There are remaining unanswered questions and issues that could impact a consumer's ability to make an informed choice of plans during enrollment periods and his or her access to medically necessary prescriptions. Issues include but are not limited to:

- Ensuring plan sponsors have the labeler codes that are subject to agreements in sufficient time to develop formularies for the following year.
    - While we understand that CMS needs proper time to develop manufacturer agreements in 2011 that prevent providing labeler codes to plans before formulary development, in future years it is important that agreements help inform formularies, especially because the 2011 exception to the definition of a Part D drug, may not be applied.
- Consideration of multi-year agreements with manufacturers.
    - It is important that there is consistency in consumer treatments and prescription regimens. Multi-year agreements would ensure that drugs covered by Part D will not change annually.
- If manufacturers will be required to enter into agreements for all of their drugs, or will they be allowed to exclude some drugs.
- What happens if a manufacturer rescinds an agreement in the middle of a plan year?
    - We are concerned that without a clear transition or exceptions policy in place, consumers could immediately lose access to medically necessary treatments causing health risks.

We ask CMS to strengthen the prospective notice requirement to consumers concerning current Part D drugs that will no longer be covered in this section and to reconsider its decision that transition requirements do not apply. Consumers and their prescribers will need notice that explains why a drug will no longer be covered under Part D. CMS should require plans to send affected consumers notices about drugs no longer covered by Part D as a result of manufacturer agreement policies that would allow an appropriate time period for the consumer to work with his or her prescriber to discuss alternative covered drugs, and to transition to those drugs. As the manufacturer agreement process will be ongoing, these notices should be required any time an agreement change implicates consumers' access to drug treatments.

We do not think that it is sufficient to distribute the list of labeler codes to Part D sponsors and to post the list on the website. We believe that notice needs to be sent directly to prescribers so they understand that drugs they might normally prescribe will no longer be covered under Part D. CMS might consider using MedLearn or other networks that reach prescribers.

Additionally, in 2011, when Part D will continue to cover drugs that are not subject to a manufacturer agreement, we request that, after the initial fill of a drug not subject to a manufacturer agreement, a notice be sent to the prescriber informing him/her that the drug is no longer covered under Part D. Consumers also need to be told that, if they enter the coverage gap, the drug will not be subject to the discount program and they will be charged the full price of the drug. CMS should have plans distribute a master list of non-covered drugs to consumers so consumers are able to adapt their treatment as necessary.

We recognize that drugs not subject to a manufacturer agreement will no longer be covered drugs. However, at least initially, consumers and their providers need time to understand that regularly-prescribed drugs may are not covered under Part D and adjust treatment methods. We therefore ask that, at least for 2012, when the effect of the changed policy may be most dramatic, consumers be allowed a limited transition policy.

The prospective notice to consumers should be provided separately from the Annual Notice of Change (ANOC), which is already confusing to consumers. We suggest both individual notices and statements on EOBs. We also suggest that a list of non-covered drugs be included in the Medicare & You Handbook. Again, the Medicare & You Handbook for 2011 should explain that drugs on the list will not be subject to the discount.

§50.2 – Exception-authorizing coverage for drugs not covered under a manufacturer discount program: We thank CMS for exercising its discretion to allow continued coverage in 2011 of drugs for which there is no manufacturer agreement. We ask CMS to ensure that such drugs not be moved to higher cost-sharing tiers than the tiers in which they were placed for 2010.

We believe that this section needs further clarification. It is not clear from the guidance whether the exception listed in PPACA that requires access to "drugs essential to the health of Part D enrollees" will be applied on an individual basis or on a program-wide basis. We believe that both options should be available.

We ask CMS to develop, with public comment, and to make publicly available the standards it will use to make exceptions on a program-wide basis. For example, in some cases there could be a time lapse between when an innovative drug or biologic is approved and when CMS engages in the manufacturer agreement process; it is important that consumers have access to these potentially life saving medications as immediately as possible. In addition, we have concerns about access to treatments if there is a category or class of drugs in which no medication is subject to a manufacturer agreement. In these cases there will be no alternative drugs for consumers to use. Lastly, there is a potential financial incentive for manufacturers to not include high cost drugs and biologics in their manufacturer agreements, which could cause access issues. Due to the serious implications of the exceptions process, we believe that exception determinations should be transparent and open to public input.

There may be situations in which the only drug available or effective for an individual consumer is not subject to a manufacturer agreement for any number of reasons including adverse side effects associated with alternative medications. If that drug is excluded, then the consumer may be denied access to a medically necessary and possibly life-saving treatment. Consumers in this situation should be entitled to use the exceptions process to demonstrate that no other medicine is effective for them. If consumers are allowed to use the exceptions process in this situation, then CMS should ensure that drugs approved through this process are not automatically placed on a specialty tier.

§70.4 Date of dispensing/no retroactivity: We ask that this section be modified to allow for retroactive coverage when a consumer receives a favorable coverage determination or favorable decision on appeal. For example, a consumer who is already in the coverage gap presents a

prescription for a brand name drug at the pharmacy and coverage is denied. The consumer purchases the drug and asks for a coverage determination. The consumer receives a favorable coverage determination or appeals and receives a favorable decision on appeal. The consumer should be entitled to receive reimbursement for the discounted cost of that drug.

This is also true for consumers who are approaching the coverage gap. A favorable coverage determination or appeal could potentially put a person into the coverage gap when they had not reached it earlier due to a coverage denial. As a result of the necessary recalculation, not only would the drug subject to the successful appeal be subject to the discount, but the cost of other drugs subject to pre-coverage gap cost sharing may require the application of discounts as well.

§80 Beneficiary dispute resolution: We ask that the second paragraph be modified to make clear that such claims are subject to the entire Part D appeals and grievance process. We suggest amending the second paragraph to read "….beneficiaries shall have access to the existing coverage determination and appeals process…."

§90 Program Oversight: In addition to the metrics included in this section, we ask CMS to include metrics involving medication switching and improved medication adherence.