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United States Senate Committee on Finance

**Medicare Prescription Drug Benefit Program:
Monitoring Early Experiences**

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**Testimony of Vicki Gottlich, Esq.
Center for Medicare Advocacy, Inc.**

Chairman Baucus, Senator Grassley, members of the Committee, thank you for the opportunity to testify today on behalf of Medicare beneficiaries concerning implementation of Medicare Part D. I am Vicki Gottlich, a Senior Policy Attorney with the Center for Medicare Advocacy, a national, non-profit, non-partisan organization that works to ensure fair access to Medicare and quality health care.

Overall, the Center has assisted thousands of Medicare beneficiaries and their helpers across the country to understand and utilize the Part D system, plan options, and rules. In our conversations with Medicare beneficiaries, their advocates, and policy-makers, we hear repeatedly about beneficiaries having insufficient information to make sound decisions about which plan to choose, to understand what should be covered, and to know how they will fare during Part D's various coverage gaps. In addition to having insufficient information, some beneficiaries are given incorrect information by plan marketing agents, and find themselves in a drug or other health plan in which they did not intend to enroll.

Beneficiaries who are dually eligible for Medicare and Medicaid are too often unable to obtain their medications due in large part to data-sharing problems among states, the Centers for Medicare & Medicaid Services (CMS), the Social Security Administration (SSA) and Part D plans. Beneficiaries also report difficulty obtaining exceptions for drugs not on a plan's formulary, for drugs with quantity limits, and for the off-label use of certain drugs. Similarly, we hear many complaints that the exceptions process is both complicated and vague.

CMS, the agency that administers Medicare, continues to tout Part D as a resounding success, while characterizing what are persistent and systemic issues as small glitches in the system. Our experience over the past year and half continues to show otherwise. Some of the most glaring and continuing problems are:

- As designed, the Part D program is immensely complicated. The program's complexities affect the ability of beneficiaries to understand the program, choose plans, pay premiums, benefit appropriately from the low-income subsidy, and utilize the exceptions and appeals process.
- The complexity of the Part D program also makes the program ripe for marketing abuses; beneficiaries who do not understand the nuanced differences among plans and plan types easily fall prey to unscrupulous sales agents.
- CMS's administration of the Low-Income Subsidy (LIS) lacks clarity and uniformity so that the subsidy too often fails to reach eligible beneficiaries.
- CMS, SSA, and Part D plans still have not developed a quick, efficient, and accurate system for transferring information about enrollment and premium payments. As a result, beneficiaries continue to have premiums withheld inappropriately from their Social Security checks, continue to be owed money for premiums inappropriately paid or withheld, and sometimes are threatened with involuntary disenrollment from their drug plan for failure to pay premiums they believed were paid.

- The Part D exceptions and appeals process is too complex and too varied from plan to plan to be adequately accessible to Medicare beneficiaries. Further, the standards for appeals are too vague and do not give adequate credence to the opinion of beneficiaries' attending physician.

The Senate Finance Committee has taken an important step to ensure that people with Medicare have access to medically necessary prescriptions simply by holding oversight hearings on Medicare Part D. We thank you for that step. We also thank Senators Bingaman and Smith for introduction of bills S. 1102 and S. 1108, to improve access to the low-income subsidy that assists with Part D premiums and cost-sharing; S. 1103, to provide additional assistance for beneficiaries in the coverage gap known as the donut hole; and S. 1107, to reduce cost-sharing for certain dually eligible beneficiaries who receive skilled nursing care while living in the community. We thank Chairman Baucus for your leadership on S. 4, concerning negotiation of prescription drug prices.

Our testimony today addresses in more detail several other issues not already the subject of legislation.

PART D IS IMMENSELY COMPLICATED. THIS COMPLEXITY MAKES CHOOSING A PART D DRUG PLAN DIFFICULT.

The Part D prescription drug program is premised on providing Medicare beneficiaries with choices about their drug coverage. The complexity of Part D, however, impedes the ability of many Medicare beneficiaries to choose a drug plan that is right for them. According to the Kaiser Family Foundation, the number of prescription drug plans (PDPs) offered in 2007 increased by 30% over the number in 2006. Only residents of Alaska and Hawaii, with 45 and 46 options, respectively, have fewer than 50 PDPs from which to choose. Of these options, only about 10% offer the standard statutory benefit.¹ That means that the other 90% vary in their premiums, deductibles, cost – sharing, and coverage in the “donut hole” or coverage gap. All drug plans vary in their formulary, drug tier placement, and utilization management tools. The number of plans and the number of variables make choice virtually impossible.

Secretary of Health and Human Services Leavitt applauded the increased number of drug plans in 2007 in a press release issued in September 2006. Health policy analysts, however, have long questioned the value of increased health care financing choices to older people and people with disabilities. They particularly question the value of health care choices when, as with Part D, the variety in plan benefit structures makes comparison more difficult. Some analysts have concluded that having to choose among many options creates a burden on beneficiaries and increases their difficulty in making an informed and meaningful decision.²

Our experience bears out the conclusion of the health policy analysts. Many drug plans made

1 J. Hoadly, et. al, *Benefit Design and Formularies of Medicare Drug Plans: A Comparison of 2006 and 2007 Offerings* (Kaiser Family Foundation., Nov.2006), <http://www.kff.org/medicare/upload/7589.pdf>.

2 See, e.g., Biles, Dallek, and Nicholas, *Medicare Advantage: Déjà vu All Over Again?* Health Affairs web-exclusive (December 15, 2004); Hibbard, Slovic, Peters, Finucane, Tusler, *Is The Informed-Choice Policy Approach Appropriate For Medicare Beneficiaries?* 20 Health Affairs 199 (May/June 2001); Schwartz, *The Paradox of Choice: Why More Is Less* (Ecco/HarpurCollins Publishers 2004).

numerous changes in their benefit design and cost-sharing in 2007. They increased premiums, increased costs for some drugs while reducing costs for others, moved some drugs to a higher cost-sharing tier, and changed utilization management tools such as step therapy, quantity limits, and prior authorization.³ Despite these changes, most beneficiaries did not re-evaluate the plan in which they were enrolled to determine whether a different plan would serve them better. CMS reported in a January 30, 2007 press release that only 7% of beneficiaries who were not eligible for the low-income subsidy changed plans.⁴ Beneficiaries and their helpers told the Center staff that they had found the process of choosing a plan for 2006 to be too complicated, and they could not face going through the process again.

Unfortunately, starting in January 2007, we also heard from beneficiaries who either did not understand the need to review their plan choice or who were not able to review the information as provided to them. The individuals were adversely impacted by changes to their plan's formulary and were "locked in" to that plan for all of 2007. For example a Rhode Island beneficiary whose native language is Portuguese and who has limited ability to read English enrolled in a high-cost plan in 2006 because it covered brand name drugs in the "donut hole" or coverage gap. He did not understand until April 2007 that the plan's coverage had changed and that he would have to pay for the drugs he needed while in the gap. The 40-page plan booklet he received for 2007 was in English, which he could not read, and did not highlight the formulary change.⁵ Had he known of the reduction in gap coverage, the beneficiary would have enrolled in a drug plan with a lower premium.

THE COMPLEXITY OF THE PART D FOSTERS MARKETING ABUSES.

Marketing scams for PDPs and Medicare Advantage plans (MAs), including MA plans with prescription drug coverage (MA-PDs), were not new to the 2006 annual enrollment period. For over a year advocates have complained about such scams as sales agents going door-to-door at senior housing facilities to solicit enrollment in MA plans; enrollment of beneficiaries with diminished capacity or limited English proficiency; targeting dual eligible beneficiaries who might not benefit from enrollment in a more costly plan; enrolling beneficiaries in a more costly PDP than the one they wanted to enroll in; or enrolling beneficiaries in an MA-PD when they wanted to enroll in a PDP.

One frequent scam during the 2006 Annual Enrollment Period involved Part D sponsors telling beneficiaries across the country that they must have a home visit to enroll in one of their PDPs. The agents who made the home visit then engaged in a hard sell to enroll the beneficiary in one of the sponsor's Medicare Advantage plans, often a private fee-for-service plan, rather than in the PDP the beneficiary wanted. A State Health Insurance Assistance Program (SHIP) counselor from Virginia who attended a sales meetings said that the salesman was so persuasive she would have enrolled in the PFFS plan, rather than the PDP, if she did not have the knowledge she has as a counselor.

³ *Benefit Design and Formularies of Medicare Drug Plans: A Comparison of 2006 and 2007 Offerings, supra.*

⁴ <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=2079&intNumPerPage=10&checkDate=&checkKey=&srchType=&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date>

⁵ See, National Senior Citizens Law Center, *Medicare Prescription Drug Plans Fail Limited English Proficient Beneficiaries* (February 2007), http://www.nslc.org/areas/medicare-part-d/article.2007-02-27.2718724527/at_download/attachment.

Beneficiaries often do not learn of the marketing error until they cannot get the health care they need or they begin to receive unexpected bills. For example, a 94-year old woman from Oxford, Mississippi discovered that she was enrolled in an MA-PD when she began getting medical bills from her doctors. Her attorney said that, although the woman cannot read, she is competent and would never intentionally enroll in a program her doctors did not accept. The woman told her attorney that she does not know how she got enrolled into the plan. She said that two men came by her house, she told them she was not interested, and asked them to leave. The attorney had to go through extensive advocacy to get her retroactively disenrolled from the MA-PD and into a PDP.

When enrollment errors are discovered, advocates report that it may take months before CMS returns beneficiaries to the traditional Medicare program and the PDP they thought they had chosen. If action is required by Part D sponsors to return a beneficiary to a less costly plan, not all Part D sponsors are willing to take that action. An advocate from Maine filed a formal complaint with CMS in April 2007 against a drug plan sponsor for “bumping up” a beneficiary dually eligible for Medicare and Medicaid from a benchmark plan into a more costly plan for which she had to pay a portion of the premium, and then refusing to take corrective action. Despite initially telling the advocate that her client would be retroactively enrolled into its basic plan, the sponsor then sent a letter saying that the client could not change plans because she was outside the annual enrollment period. The statement is incorrect, since Congress protected “dual eligibles” by allowing them to change drug plans at any time. The plan sponsor continued to bill the client for premiums while raising other arguments against retroactive disenrollment. The sponsor finally agreed to help the client, but said it would not change any other enrollments.

THE COMPLEXITY OF PART D CAUSES SPECIAL PROBLEMS FOR LOW-INCOME BENEFICIARIES.

One of the major changes made by Part D is the requirement that beneficiaries who are eligible for both Medicare and Medicaid (dually eligible beneficiaries) get their prescription drugs through Medicare Part D. On January 1, 2006, these people lost their eligibility for prescription drug coverage under Medicaid. Further, Medicaid beneficiaries who become newly eligible for Medicare lose their Medicaid drug coverage when their Medicare eligibility begins, even if they are not enrolled in a Medicare prescription drug plan. Such beneficiaries may experience drug coverage gaps when they are first eligible for Medicare due to time lags in the transmission of information about their new dual status, which must flow from the state to CMS. This change in drug coverage for low-income beneficiaries was the source of some of the most serious and significant problems when Part D began in 2006. Problems with Part D drug coverage for dually eligible people persist.

Although CMS automatically enrolls dually eligible beneficiaries into plans, effective the first day of the month in which they become dually eligible for both Medicare and Medicaid if they have not chosen a plan themselves, the enrollment may not, in fact, have been effectuated by the time they lose Medicaid coverage. They are entitled to reimbursement for out-of-pocket costs above the level of their subsidized co-payments; however, their low income status may make it impossible for them to actually pay out-of-pocket. Those beneficiaries who choose a plan, rather than accept auto-enrollment, must affirmatively request through their plan that their enrollment be retroactive to the date they became dually eligible. The plan must submit the request to CMS.

CMS has a point of service (POS) system that allows a new dually eligible beneficiary for whom plan enrollment information is not available to receive drug coverage at the pharmacy (the “point of service”) upon a showing of proof of Medicare and Medicaid enrollment. However, this system is not available to other dually eligible persons who experience difficulties at the pharmacy, including those for whom CMS’s records show enrollment in a specific plan. Moreover, many pharmacists remain unfamiliar with the POS system and, even if they know about the system, they are not obligated to use it. If pharmacists use the POS system in error, the pharmacy is liable for the difference between the billed amount and the full cost-sharing due. Ironically, when new duals are already enrolled in a plan that did not acknowledge their enrollment, the POS option does not work for them and they are worse off than if they had not been enrolled in a Part D plan at all.

As I stated earlier, dually eligible persons are entitled by law to change plans at any time. They do so at their peril, however. Considerable confusion often occurs when plan changes are made and it may be difficult to understand which plan is responsible to pay for a drug during a plan-change transition.

Additionally, Medicare beneficiaries becoming newly eligible for Medicaid experience delays in getting access to their low-income subsidy. Data are transmitted by the states monthly; a beneficiary whose dual status is determined the day after the monthly transmission will not appear as a dual-eligible until the following month. For example, a new dually eligible beneficiary from Florida has been unable to get his Hepatitis C medicine because he cannot afford the \$514.87 co-pay charged by his Part D plan. He became eligible for Medicaid, and therefore should have been automatically deemed eligible for the low-income subsidy (LIS), on March 1, 2007. However, the state failed to transmit his files to CMS with its March submission, so CMS had no record of his LIS eligibility. As of April 25, 2007, CMS has either not received, or not coded and uploaded, the April submission from the state, so his LIS –eligible status was still not recorded in CMS systems. The POS system has not been effective for the beneficiary. He reported that when he went to his pharmacy in early April, the pharmacy was not aware of the procedure for billing the point of service system. The beneficiary is experiencing adverse health consequences as a result of not having his medicine.

The Florida beneficiary’s story illustrates the complexities and importance of the data-sharing that is required to ensure that dual-eligible beneficiaries do not experience coverage gaps or gaps in their entitlement to lower cost-sharing when they become dually eligible. It also illustrates the complexity of resolving such problems, because so many entities (the state, CMS, the pharmacy, the drug plan, and sometimes SSA) are involved and each may be required to take some action that depends on the prior actions of another entity.

RE-DETERMINATIONS OF ELIGIBILITY FOR LOW-INCOME SUBSIDY ARE MADE THROUGH MULTIPLE MECHANISMS, LEADING TO CONFUSION AND ERRORS.

Low-income beneficiaries must re-qualify for the Part D low-income subsidy (LIS) each year. Since several paths exist for re-qualification, the process is confusing, especially for those whose circumstances fluctuate over the course of a year. Medicare beneficiaries who are also enrolled in

Medicaid, a Medicare Savings Program,⁶ or SSI are “deemed eligible” for LIS and do not have to apply. If individuals were on the rolls in one of these programs in July of 2006, they were to be “re-deemed” eligible for the subsidy for 2007. However, plans do not always have correct information about beneficiaries’ subsidy-eligibility status, and, sometimes, neither does CMS. For example, on January 2, 2007, a dually eligible resident of Virginia who should have been deemed eligible for the low-income subsidy was told by her pharmacy that she needed to meet the Part D \$265 deductible, although people entitled to the LIS do not have a deductible. The woman had no changes in her income, assets, or program eligibility for SSI, Medicaid, or Medicare. Her Medicaid eligibility worker called her drug plan and was told, incorrectly, the woman had lost her low-income subsidy eligibility.

Anticipating such problems, CMS sent a memorandum to Part D plans in December 2006 to explain that they must use the best available data to reconcile status when a beneficiary believes he or she is still eligible for the subsidy. The beneficiary may present proof of eligibility, such as a Medicaid card, at the pharmacy and the plan should follow up to collect the evidence. In the case of the Virginia beneficiary, and in other similar situations, Part D plans have failed to follow the CMS memorandum and to inform pharmacists and beneficiaries about presenting evidence of LIS eligibility.

When a Medicaid beneficiary loses eligibility for Medicaid benefits, states have an obligation under Medicaid law to determine if that person is eligible for Medicaid under another category of the state’s program. For example, someone losing Medicaid eligibility might, nonetheless, still be eligible for a Medicare Savings Program, since these income and resource limits are higher than Medicaid in most states. If states routinely undertook these new determinations of eligibility for other Medicaid benefits before terminating people from the program, fewer LIS recipients would find themselves in the limbo of not knowing about their LIS status. Similarly, even for those individuals no longer eligible for any benefits under the state Medicaid program, the state or SSA could undertake independently to determine their eligibility for the LIS, which has income and resource limits that are higher than those of most states’ Medicaid programs.

BENEFICIARIES CANNOT BE GUARANTEED THAT PROBLEMS WITH THE PREMIUMS WITHHELD FROM THEIR SOCIAL SECURITY CHECKS WILL BE RESOLVED – EVER.

Paying premiums for the Part D plans they have chosen is a challenge for many beneficiaries. Many beneficiaries chose to have Part D premiums withheld from their Social Security checks and paid directly to their plans, as they are accustomed to doing with Part B premiums. For some, Social Security withholding was never implemented. For others, Social Security withholding was implemented incorrectly. Some beneficiaries received refunds of their withheld premiums that they were not owed, while others wait months to receive the premium refund that is owed them.

Beneficiaries who experience premium problems have no place to turn; no entity is willing to take responsibility to resolve the problems. CMS tells beneficiaries to call their drug plan, drug plans tell

⁶ The Medicare Savings Programs pay the Part B premium and, for those eligible for the Qualified Medicare Beneficiary (QMB) program, Medicare cost-sharing.

beneficiaries to call SSA, and SSA tells beneficiaries to call CMS. I have been called by several Medicare beneficiaries who were given my name and telephone number by SSA and told to call me, even though I have no authority to stop withholding and order a refund. Advocates across the country report that regional CMS offices have told them that their clients will be put on “the list” maintained by the regional CMS office, and that the problem may not be resolved for as much as a year.

The impact on beneficiaries of paying multiple premiums and/or of awaiting refunds of premiums inappropriately paid can be severe. Some beneficiaries whose drug plans claim that they have not received premiums withheld from the beneficiaries’ Social Security checks have received dunning letters and are worried about their credit rating. As one beneficiary told me, the money she is owed may not seem like a large amount to the government or to her drug plan, but it is a large amount of money to her.

The problems of a couple from Oklahoma are typical of the time and effort that beneficiaries and their helpers must undergo in order to try to resolve problems. Although their Part D premiums were being withheld from their Social Security checks, the couple received a premium – due notice from their drug plan in September 2006. Calls and visits to SSA did not resolve the issue, and they received another premium-due notice in October. They contacted their drug plan, SSA, which said to call Medicare, and Medicare, which did not solve the problem. Despite changing to a different drug plan for 2007, for which they pay directly, premiums for a plan offered by the original plan sponsor continue to be withheld. The couple also received collection notices in March for the 2006 premiums which had already been paid. Calls to SSA lead to a referral to the state insurance commissioner, which lead to a referral to CMS, which lead back to the drug plan. The drug plan claimed not to have a record of the October request to stop premium withholding. The couple again requested the plan to stop withholding premiums for the plan in which they no longer are enrolled. On April 20, the plan told the couple that CMS acknowledged the stop-withhold request, the request would be effective May 31, 2007, and CMS estimated they would get their refund in about six months. The plan representative would not provide written confirmation of these assertions.

Despite multiple efforts, the Oklahoma couple cannot be assured that the improper withholding of premiums will be stopped. Nor do they know if and when they will receive a refund of the money due them. And, when they receive the refund, they will not receive any interest on the improperly held amounts.

THE PROCESS FOR GETTING COVERAGE OF DRUGS THAT ARE NOT ON A DRUG PLAN’S FORMULARY IS CONFUSING, COMPLICATED, AND OFTEN NOT UNDERSTOOD BY BENEFICIARIES AND THEIR HELPERS.

In promoting Part D, CMS assured beneficiaries that they would have access to all of their medically necessary prescription drugs. What CMS failed to explain to beneficiaries is that they might have to file for a “coverage determination” and pursue an appeal if the drug they need is not on their plan’s formulary or is subject to certain restrictions, such as a limitation on the number of dispensable pills (“quantity limits”) or the need to request the plan’s permission before the drug is prescribed and paid for (“prior authorization”). The process for requesting a coverage determination and then an appeal is complicated, and most beneficiaries do not even understand this process, or the fact that they have the right to seek coverage for a drug not on their plan’s formulary.

A. Beneficiaries Are Not Adequately Informed Of Their Right To Request A Coverage Determination And File An Appeal

Under Medicare regulations, the Part D appeals process cannot begin unless and until a beneficiary who is denied coverage for a drug at the pharmacy affirmatively requests a formal “coverage determination” from his or her Part D drug plan. A coverage determination can only be issued by the drug plan itself; the denial at the pharmacy counter has no legal effect. The formal coverage determination from the plan should explain why the plan will not pay for the drug and how to start the appeals process.

Most beneficiaries who are denied coverage for their prescribed medications need to request a special type of coverage determination known as an “Exception.” An Exception may include a request to cover a drug that is not on the formulary, a request to reduce the cost-sharing for a drug, a request to provide a larger dose of a drug than the formulary limit, or a request to receive the prescribed drug without first trying a less expensive drug (“step therapy”). An Exception may also include a request to provide a drug without first getting prior authorization from the drug plan.

Unfortunately, beneficiaries are not adequately informed of the need to request a coverage determination. As a consequence, they never contact their drug plan for a coverage determination and they never enter the appeals process. Advocates continue to report that pharmacies are not complying with the regulatory requirement to either post or hand to beneficiaries the CMS-approved notice, “*Medicare Prescription Drugs and Your Rights*,” which explains in general the right to contact one’s plan to request an Exception or other coverage determination. Even if the notice is posted, posting provides very little protection. The notice is often placed where it is difficult to read.

Beneficiaries who use a mail-order pharmacy may receive no information at all. For example, if a Maryland beneficiary had not called her mail-order pharmacy to inquire about the status of her refill request, she never would have been told that she needed to request prior authorization from the drug plan before it would cover her drug. Even after she called, the mail-order pharmacy never sent her the notice explaining her rights. Thus, she did not know that she had a right to request an Exception to the prior authorization requirement.

Neither CMS nor the plans take responsibility when advocates complain that beneficiaries are not being informed of their rights to ask for an Exception and then to appeal. CMS says the plans are required to ensure distribution of the generic notice; plans claim they have done their job in educating pharmacies.

Advocates also complain that beneficiaries are not being informed of their appeal rights at later stages in the appeals process. A drug plan is required to provide both the beneficiary and the prescribing doctor who filed the Coverage Determination request with a standard Coverage Determination notice developed by CMS. Despite the requirement to use the standard form, which provides reasons for the denial and an explanation of appeal rights, some plans fail to provide enrollees with the information they need to request an appeal. For example, instead of sending the beneficiary the standard Coverage Determination, an Arizona drug plan sent the prescribing

physician a letter that made no mention of the reasons for denial or of appeal rights. The letter simply stated that the request for prior authorization was denied, and that the physician should consider the alternative drugs on the plan's formulary.

Similarly, a beneficiary who requests a plan Redetermination of an unfavorable Coverage Determination is entitled to receive written notification of an unfavorable decision. The written notice must include the reasons for the adverse decision and the right to request a Reconsideration, the next step in the appeals process. Nevertheless, advocates report their clients have received unfavorable Redetermination letters that tell the beneficiary to contact his/her physician for alternative medicines, and to check the plan's formulary for covered medications. No mention is made in these notices of appeal rights.

B. Part D Plans Use A Number of Tactics to Undermine the Exceptions and Appeals Processes

Even if the pharmacy tells a beneficiary that prior authorization from the plan is required before a drug will be covered, or that another drug must be tried first before the prescribed drug will be approved, or that the drug is not on the plan's formulary, the beneficiary still does not have all the information he or she needs in order to take action to get his or her medication. Drug plans do not make available on their web site or through their customer service centers information about the utilization management tools that apply to particular formulary drugs and/or the criteria they use to evaluate a prior authorization request. Thus, beneficiaries, their doctors, and their advocates do not have the information they need to support a request for prior authorization or a request for an Exception. Worse, some plans use the prior authorization and Exceptions processes as a way to delay providing and paying for prescribed medications.

The following examples are typical of the difficulties beneficiaries encounter when trying to use the prior authorization and Exception processes.

1. A dually eligible beneficiary from Massachusetts cannot obtain coverage for a drug that she had successfully taken for eight years. Her drug plan requires her to go through "step therapy" and to try other drugs on the plan's formulary. She has tried, seriatim, each of the alternatives; each time her doctor has requested and been denied prior approval. Her doctor is currently appealing denial of prior approval after the beneficiary unsuccessfully tried every suggested alternative. The beneficiary is having difficulty breathing, is not sleeping, is nauseous, miserable and, her advocate says, "in tears."

2. On April 7, 2007, a Connecticut beneficiary with multiple health problems was prescribed a broad spectrum antibiotic to be taken for seven consecutive days. Her pharmacy told her that the drug plan would not cover the medication without providing further explanation or explanation of appeal rights. Because the beneficiary is a former registered nurse, she knew to call her drug plan to inquire about the prescription. Although the Evidence of Coverage provided by the drug plan says the drug is on its formulary and does not describe any limitations to coverage, the drug plan call center representative said the drug is subject to prior authorization. The representative became exasperated at the beneficiary's insistence that the drug should not be subject to prior authorization and told her no one was available to do prior authorization during the weekend. When she asked what people who need prior

authorization over the weekend should do, he told her she needed to get prior authorization Monday – Friday, said he would not talk to her anymore, and hung up.

The beneficiary called the plan on Monday, April 10, and spoke with a different representative who did not fax a form for her doctor to complete until the next day. The doctor returned the form that same day, received a request from the drug plan for additional information, and returned the information immediately. Because of the delay in the start of the prescribed medicine, the seriousness of the beneficiary's illness, and the beneficiary's compromised health history, the doctor gave the beneficiary a sample pack of the medicine.

CMS regulations and guidance require drug plans to respond to coverage determination requests as expeditiously as the beneficiary's condition requires, but no later than within 72 hours or 24 hours if expedited consideration is warranted. The beneficiary received a coverage determination on April 16 denying coverage. The letter, dated April 12 and postmarked April 13, said she was required to try other medicines first, even though the Evidence of Coverage and the Plan Finder on the Medicare website do not indicate that step therapy is required. The client received a second letter on April 20, also dated April 12 but postmarked April 14, that said coverage was granted. The letter said the pharmacy was informed of the approval but the pharmacy says they received nothing. Although regulations require the drug plan to contact the beneficiary, the drug plan told her she should have called her doctor or her pharmacy to find out if the exception was approved.

3. A beneficiary from New York City needed a particular medication for chronic reflux to minimize post-operative complications from a thyroidectomy. He had tried six other medications, but none was effective. The day before the surgery his Part D plan still had not provided the beneficiary or his doctor with written notice of denial of the prior authorization request and appeal rights, although the request had been made well in advance of the surgery.

In addition to requiring doctors to provide more and more information, plans continue to claim they never got a Coverage Determination or Redetermination request, so they never issue a decision. For example, a doctor in Maine faxed the blood test results requested by a drug plan three times, but the drug plan kept saying it had not received them. Advocates also report faxing exception and redetermination requests only to discover that those requests do not get forwarded to the appropriate person or office, or they get forwarded several days after they are faxed. Such tactics discourage doctors from seeking Exceptions and Coverage Determinations.

3. The Part D Appeals Process Includes Conflicting Directives Concerning The Effect Of The Attending Physician's Opinion On An Exception Request And Appeal

A beneficiary must have the support of the prescribing physician in order to succeed with an exceptions request. Indeed, the Medicare statute makes the opinion of the attending physician concerning his or her patient's need for a non-preferred drug the controlling factor in determining coverage. However, the Part D regulation specifically downgrades the effect of the physician's opinion to such an extent that it is not clear whether any deference is given. Thus, while beneficiaries must obtain a supporting document from their physician even to enter the appeals

process, Part D plans are not required to respect the physician's opinion.

For example, a drug plan denied a coverage determination request for a non-preferred formulary drug filed by a doctor on behalf of a beneficiary from Maine. Although the doctor listed the generic version of the plan's formulary alternative as one of the many medications the beneficiary had tried for her chronic condition, the plan stated that its claims history did not show that she had tried the drug. Because the drug plan does not have to respect the physician's opinion, the drug plan ignored the medical records created and supplied by the doctor to show that the beneficiary had already tried, unsuccessfully, the formulary drug.

4. Difficulties in establishing proof of safe and effective off-label drug use

The use of drugs "off-label" is legal in the United States and is governed by strict rules for marketing. In many situations, physicians and their patients have determined over time that certain drugs approved by the FDA for one purpose also help with a different medical problem. Yet Part D plans do not defer to the opinion of the treating physician, even when the off-label use is supported by scientific literature, proven safe and effective over a substantial amount of time, and covered by the beneficiary's state Medicaid program.

The Medicare statute allows for coverage of certain off-label drug uses if they are included in one of three enumerated compendia. Unfortunately, beneficiaries, their families and their advocates who are not medical professionals do not have access to these compendia, making appeals of these cases very difficult. Some advocates have turned to state resources, including state-funded hotlines, for assistance, but these resources are limited, inefficient and incomplete. Without direct access beneficiaries and advocates cannot determine whether they have found all the entries in which a drug is mentioned, or whether the entries they have been faxed are the most up-to-date and complete. In essence, Congress and CMS have established a standard of proof which the average beneficiary cannot meet because of lack of access to the required information source.

PART D COMPLAINT MECHANISMS ARE NOT PROMPT OR RELIABLE, AND CMS IS UNWILLING TO TAKE ENFORCMENT ACTION.

CMS has established a number of mechanisms through which beneficiaries may seek redress of problems with their drug plan. Most of them do not work well. Beneficiaries who are not happy with their drug plan are urged to file a complaint by calling the Medicare hotline, 1-800-MEDICARE. As you are aware, the General Accountability Office has issued a number of reports detailing problems with the Medicare hotline in terms of response time and accuracy of information.⁷

Despite assurances from CMS that its hotline is responsive, advocates continue to find otherwise. For example, a Massachusetts attorney who tried to call 1-800-MEDICARE late in the afternoon of

⁷ See, e.g., GAO, *Communications to Beneficiaries on the Prescription Drug Benefit Could be Improved* (GAO 06-664, May 2006), <http://www.gao.gov/new.items/d06654.pdf>; GAO, *Accuracy of Responses from the Medicare 1-800-Medicare Help Line Should Be Improved* (GAO 05-130, December 2004).

Monday, April 23, 2007 got a recording that due to high call volume she could leave a message and someone would call her back. She hung up, called again, and got the same recording. She proceeded to leave a call-back number and was told a representative would call back in a few days. She could only leave a telephone number and whether she wanted to be called back in the morning or evening. When she had not received a phone call by 3:00 pm on Friday, April 27, she tried again, only to hear a recording that she would have to wait on hold for 25 minutes. The attorney hung up, called again, and was told to leave her call-back information. If she had been a beneficiary with an emergency drug problem she would have been left without any assistance.

An advocate from California reported receiving the same message when she called 1-800-MEDICARE on behalf of a client who is deaf. The advocate pointed out that if her client, who uses a video relay system rather than TTY, had been the one who got the recording, the client would have had no way to leave both the video relay number and her home number. The advocate realized the problem when she was not even allowed to leave her own extension number.

Some advocates have developed relationships with their regional CMS offices and can call their regional office contacts when egregious problems occur. At times, however, regional office staff have been so swamped with complaints that they have told advocates not to call them, but to go through the 1-800-Medicare system.

For many beneficiaries and advocates, filing a complaint with 1-800-MEDICARE, or even with the regional office, is like filing a complaint into a black hole. We do not know what, if any, corrective action has been taken by CMS about such complaints as marketing abuses, failure to comply with exceptions and appeals time lines and notice forms, changes in plan formularies without the required notice, and inconsistencies between plan information and the CMS web-based plan finder tool.

When national advocacy organizations raise systemic issues with the CMS central office, we are always asked for specifics: the specific pharmacy that does not post or hand out the information to call a drug plan; the specific beneficiary whose appeal was not acted on in a timely manner or who received incorrect notice; the specific beneficiary who was enrolled in a more costly drug plan than the drug plan she wanted. We raise these issues with CMS central office not because we want redress for the individual beneficiaries involved. Often we have already talked with the regional office on behalf of the beneficiary or moved to the next step in the appeals process. We alert CMS because we want them to address the problem on a system-wide basis or take corrective action against the drug plan in question. They have largely been unwilling to do so.

Another common response from CMS is that we should work the problem out with the drug plan. We and other advocates do, in fact, have contacts with some of the drug plans, but those contacts are no substitute for enforcement by CMS. After I raised concerns at a meeting with CMS about a particular plan that consistently failed to comply with appeals time frames and other requirements, I received a phone call from a representative of the plan. The advocates whose complaints I voiced talked with the representative. Nevertheless, the same plan continues to ignore CMS regulations and guidance about Part D appeals. Some of the examples in my testimony are from that plan.

RECOMMENDATIONS FOR CONGRESS

Based on our work on behalf of Medicare beneficiaries, the Center for Medicare Advocacy has concluded that many of the implementation problems with Part D are inevitable given the design of the program. The combination of private and public entities adds too many complications, as is well shown, for example, by the problems created in withholding premiums from Social Security checks. When two government agencies and their contractors plus thousands of private plans are involved, the number of problems increases exponentially, and the lines of responsibility for solving the problems remain muddled.

Therefore, the primary recommendation of the Center for Medicare Advocacy to Congress is to redesign Medicare Part D to create a benefit that is standardized, available throughout the country, and administered through the traditional Medicare program. Such a system would be more valuable for more beneficiaries and more cost-effective for taxpayers.

Short of redesigning Part D, Congress could take a number of steps, in addition to those already contemplated in the bills mentioned at the beginning of this testimony, to improve the Part D program. They include:

1. Improve the ability of beneficiaries to make a reasoned and informed choice about drug coverage.
 - Limit the number of Part D plans, both PDPs and MA-PDs, offered in each region.
 - Expand oversight to ensure that information provided to beneficiaries about their plan choices is accurate and understandable
 - .Strengthen requirements to ensure that information is made available in the language and/or alternative formats beneficiaries require.
 - Authorize the National Association of Insurance Commissioners (NAIC) to develop standardized Part D benefit structures, similar to the standardized Medicare supplemental insurance (Medigap) plans, so beneficiaries can compare plans more easily.
2. Protect beneficiaries who did not understand changes in their drug plan.
 - Extend to Part D plans the open enrollment period for Medicare Advantage plans that runs from January 1-March 31 each year.
 - Allow Part D plan enrollees the opportunity to change plans as frequently as CMS allows plans to change their formularies.
3. Improve the Part D exceptions and appeals process.
 - Require notice of an adverse coverage determination to be provided electronically at the pharmacy counter. The notice should include reasons for the denial, information sufficient to request an exception, and information about exception and appeal rights.
 - Require Part D plans to give deference to the opinion of the beneficiary's attending physician when making coverage decisions.
4. Authorize Part D coverage for off-label uses of drugs that are supported by peer-reviewed studies, are proven safe and effective over a substantial period of time, are covered by the beneficiary's state Medicaid program, or are listed in one of the three compendia currently

included in the Medicare Act, and require that access to the compendia be made available, free of charge, to beneficiaries pursuing an appeal.

5. Require CMS to establish expeditiously a full system of real time data-sharing among all entities involved in Part D, including CMS, SSA, drug plans, and other contractors. Congress should require CMS to report on its strategies to resolve these problems effectively and within a specific time period, and should require periodic status reports from CMS. The data-sharing system should include mandatory fail-safe systems to ensure that persons who are dually eligible for Medicare and Medicaid do not experience gaps in either their drug coverage or their low-income subsidy.
6. Continue oversight of CMS to ensure that CMS exercises its enforcement authority to take actions against Part D plans that fail to comply with Part D statutory, regulatory, and contractual requirements.

The Center for Medicare Advocacy again thanks the Senate Finance Committee for holding this oversight hearing on Medicare Part D implementation. We appreciate the opportunity to share with you the experiences of our clients and of Medicare beneficiaries and their advocates across the country. We look forward to working with the members of this Committee on matters related to Medicare prescription drug coverage.