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January 11, 2011

Donald M. Berwick, M.D.  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, SW  
Washington, DC 21244-1850

Re: **CMS-4144-P**

Dear Dr. Berwick:

National Patient Advocate Foundation (NPAF) would like to thank you for the opportunity to comment on the Proposed Rule entitled "Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Proposed Changes," which was published in the *Federal Register* on November 22, 2010.<sup>1</sup> NPAF is a non-profit organization dedicated to improving access to healthcare services through both federal and state policy reform. Our mission is to be the voice for patients who have sought care after a diagnosis of a chronic, debilitating or life-threatening illness. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive direct, sustained case management services from our companion organization, Patient Advocate Foundation (PAF). In fiscal year 2009 (July 1, 2009 – June 30, 2010), PAF resolved 64,188 patient cases and received more than four million additional inquiries from patients nationally.

Over the years since the implementation of the Medicare prescription drug benefit in 2006, CMS has undertaken numerous rulemakings to refine the Part C and Part D prescription drug programs. Many of the changes made to the regulations governing the programs have strengthened beneficiary protections and simplified or clarified program operations. NPAF consistently has been supportive of the agency's efforts.

<sup>1</sup> 75 *Fed. Reg.* 71190 (Nov. 22, 2010).

We are writing today to applaud many of the program refinements detailed in this Proposed Rule. Regardless of whether the changes being proposed are intended to implement the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively, the Affordable Care Act or ACA), codify existing sub-regulatory guidance, or make other program modifications, we view the Proposed Rule as a clear demonstration of CMS' commitment to administering Part C and Part D in ways that value the needs of Medicare beneficiaries. For that, we thank you.

Our comments are grounded in the experiences of the PAF professional case managers. These individuals specialize in mediation, negotiation, and arbitration to advocate on behalf of patients experiencing issues with access to care, job retention and debt crisis due to a chronic, life-threatening or debilitating illness. They provide *pro bono* services to tens of thousands of patients annually, approximately 75% of whom are covered by Medicare. Our comments identify aspects of the Proposed Rule that we wholeheartedly endorse and support, provide substantive responses to several of the questions put forward for comment, and include recommendations for modifying or expanding certain of the contemplated changes.

### **Proposals that Limit Cost Sharing Obligations**

Our case managers have seen firsthand the access problems that can result when a Part C enrollee fighting a catastrophic illness is faced with cost-sharing obligations well in excess of those under traditional fee for service (FFS) Medicare. When health reform legislation was working its way through Congress, we supported the ACA § 3202 imposition of the FFS cost-sharing cap on chemotherapy administration services, renal dialysis services, skilled nursing care and other services identified by CMS as requiring a high level of predictability and transparency for beneficiaries.

We are extremely pleased with the Proposed Rule's extension of the cost-sharing cap to § 1876 cost contracts so that all Medicare beneficiaries have the benefit of the ACA cost-sharing protection regardless of whether they have elected FFS Medicare, a Medicare Advantage (MA) plan or a § 1876 cost contract. Because over 75% of the patients served by PAF in fiscal 2009 had cancer, we loudly applaud CMS' decision to include radiation therapy services along with chemotherapy drugs, other chemotherapeutic related agents, and drug administration services as services covered by the cost-sharing cap. We are equally pleased that home health services and the first 20 days of skilled nursing care would always be free of cost sharing under the Proposed Rule. Such transitional services can be critically important to patients with chronic, debilitating and life-threatening diseases.

We also supported ACA § 3309 during the Congressional debate. This provision eliminates Medicare Part D cost-sharing for full-benefit dual eligible beneficiaries receiving home and community-based services under § 1115 or § 195 waivers or through a Medicaid managed care plan, thereby making it easier for many low-income frail elderly to choose to receive care at home rather than in an institution.. We recognize that ACA gave CMS the discretion to set the start date for this ban on cost-sharing. We commend CMS for electing January 1, 2012, which is the earliest effective date permitted by statute.

ACA § § 4103 and 4104 created new coverage for “annual wellness visits” and established a requirement that no cost-sharing may be charged to beneficiaries under FFS Medicare for wellness visits or Medicare-covered preventive services graded as an A or B by the U.S. Preventive Services Task Force. We understand from conversations with patients as well as from published studies that cost-sharing requirements can pose a significant barrier to the utilization of preventive services – particularly relatively expensive preventive services such as colonoscopies – even if the service is covered by Medicare.

Because we know that early detection of cancers can save lives and that other preventive services can improve the quality of life, we believe that the utilization of appropriate preventive care should be strongly encouraged. Moreover, we think the elimination of cost-sharing obligations for such services is the incentive most likely to be effective. We see no reason why this logic should not hold regardless of whether a beneficiary has elected to participate in FFS Medicare, an MA plan or a § 1876 cost contract. Therefore, we are gratified that the Proposed Rule would codify the requirement that MA and § 1876 plans contracts cover in-network Medicare-covered preventive services at zero cost sharing.

We also commend CMS for establishing mandatory maximum out-of-pocket amount requirements on total enrollee cost-sharing for Parts A and B applicable to local MA plans beginning in 2011. We realize that regional PPO plans have been required to set such maximums on in-network services as well as catastrophic limits inclusive of both in- and out-of-network cost sharing for Parts A and B since 2003. Those limits are, however, determined by the MA plan, not CMS, and they vary from plan to plan. The Proposed Rule would extend the imposition of the CMS-set limits, which will change annually, on both local and regional plans. NPAF applauds this change because it will protect beneficiaries facing a serious illness from unexpected costs that could, under some plans, be inordinately high. It also will facilitate plan comparisons by removing a significant but typically overlooked factor from the task. We welcome CMS’ proposal to prohibit tiered cost-sharing in MA plans for the same reasons.

### **Proposals that Limit Beneficiary Confusion and Facilitate Informed Enrollment Choices**

We are in full agreement with CMS’s stated goals of protecting beneficiaries from confusion, discriminatory cost sharing, and participation in any but the highest performing of health plans. NPAF and PAF are committed to those same goals. The PAF case managers know from experience that the steps CMS took in 2009 in furtherance of these goals resulted in clearer differences in the plan options available to beneficiaries during 2010. Furthermore, they believe those differences facilitated the plan selection process for many beneficiaries. We note, however, that the screening processes that CMS used to achieve more meaningful distinctions between plan options last year were applied at the application process when plans have an opportunity to address deficiencies and appeal decisions. They were not applied when bids were being reviewed, as CMS is now considering doing for plan years after 2011.

We recognize that ACA § 3209 gave CMS the discretionary authority to deny bids submitted by MA organizations and prescription drug plans that propose significant increases in cost sharing or decreases in benefits. We are not convinced, however, that denying Part D and MA plan bids based on factors such as premium increases, the number of plans already in a service area or,

except in the most egregious situations, quality rates at the bid-review stage is the best way to ensure that beneficiaries obtain value for their Medicare prescription drug benefit dollars. Certainly, if CMS decides to take the tact, it must establish due process opportunities for plans similar to those available now at the application stage. Otherwise, some potential plan sponsors may not be will to participation in the program.

From NPAF's perspective, allowing a multiplicity of plans appears to have stimulated competition and resulted in a Medicare drug benefit that costs beneficiaries significantly less than Congress anticipated. It certainly has provided beneficiaries with choice and may be one of the key reasons why the voluntary prescription drug benefit has been so popular and widely used.

We recommend that CMS try a combination of other approaches to ensure that beneficiaries are positioned to select an appropriate plan for their particular circumstances and obtain value for their premium and co-payment/co-insurance dollars. We commend CMS for continually enhancing and improving the Plan Finder tool available at Medicare.gov. Nonetheless, much still remains to be done to ensure that beneficiaries do not inappropriately make decisions based solely on cost but rather take a more holistic, personalized approach that looks at the details of the various coverage options available to them in the context of their health situation.

PAF case managers are of the view that the Medicare website still does not allow clear enough comparisons of plan features. There needs to be a way to select plans for side by side comparisons of critical plan features. We note that CMS is proposing to amend the regulations governing the advanced notice of change and evidence of coverage documents that must be furnished to all plan enrollees at least 15 days before the annual open election period. The enhanced forms would have to include a personalized dollar estimate of the beneficiary's out-of-pocket costs in the coming contract year based on his or her use of services in the current contract year. We applaud this decision and suggest that the comparison show not only aggregate cost but also cost for individual commonly used services such as a physician office visit, and X-ray, etc. We would also like to see side by side comparisons of costs for all drugs being taken by the beneficiary at the time the document was prepared. We suspect that similar formats could be adopted for same-year comparisons of different plans and comparisons of the cost under one plan of using different mixtures of brand and generic drugs. For ease of analysis, such comparisons could involve graphs or, at a minimum, the presentation of data for different years or different plans in different color types.

Many individuals who call PAF are able to pull data from the Medicare.gov site and identify available plans. They do not, however, always know what to do next. We recommend that CMS add a tutorial on its website that provides, in layperson's language, a step-by-step guide on how to complete a plan search and "translate" the information found. The tutorial needs to contain a glossary of insurance terminology because a surprising number of the Medicare patients that call PAF for help do not fully understand basic pharmacy benefit concepts such as formularies and tiers. They also do not appreciate how to address situations where the physician has instructed use of a brand drug when a generic is available and the Plan Finder is substituting that. Nor do they have a sense of how to deal with anticipated needs for additional or different medications during the course of the year.

Some beneficiaries do not have family members or other caregivers to assist them. Even some that do will never be able to sort out their prescription drug coverage choices without individual assistance from someone else. Many such beneficiaries would prefer a face-to-face interaction rather than a telephone contact. The result of this preference often is that the beneficiary will seek out advice from an insurance company salesman without taking into account that a salesman may not have the beneficiary's best interest in mind. PAF has assisted many callers who found themselves enrolled in the wrong plan based on enrollment decisions while meeting with an insurance company representative. The type of issues that can arise when patients rely on sales representatives for enrollment advice is illustrated by the report in Exhibit 1 on a case recently resolved by a PAF case manager.

In recognition of the need that some beneficiaries have for personal guidance, we recommend that the Medicare Plan Finder website instruct beneficiaries who want more personalized assistance that goes beyond that available at 1-800-MEDICARE to contact a local SHIPS office or Department of Aging. Links to search functions that allow users to locate addresses and phone numbers for these organizations would also be helpful, particularly if the search function runs off of zip codes and provides a list of sites within a 10-20-mile radius of the individual's home. 1-800-MEDICARE should be prepared to provide such guidance when beneficiaries indicate they need more help than has been provided or seem frustrated as a call comes to a close. We also encourage CMS to consider placing CMS-certified advisors at these offices and/or at Social Security offices to answer Medicare health or drug plan questions. The availability and effectiveness of assistance through 1-800-MEDICARE is simply not sufficient. Far too often, beneficiaries report becoming discouraged by the lengthy wait times. Far too often, the Medicare line refers patients to the Medicare website as the tool to utilize for search and enrollment without effectively answering the individual's questions or understanding the beneficiary's inability to access or use the website. Another approach could be to open CMS enrollment centers where an in-office appointment could be scheduled or an over-the-phone assistance call, possibly a video conference call, could be placed to more sophisticated counselors than those available through 1-800-MEDICARE.

To ensure that any individuals providing enrollment assistance are properly trained and qualified, we urge CMS to develop and require successful completion of a certification test by all CMS and contractor employees engaged in assisting beneficiaries with enrollment issues. The same or a similar test also should be a mandatory part of the licensing examinations required of insurance agents and brokers allowed to sell MA plans or Medicare prescription drug plans. In addition, the certification test could be used to assess the quality of help available from nonprofit organizations like PAF willing to partner with CMS to provide beneficiaries with enrollment guidance. Such organizations have no stake in the plan choice made and are positioned to instill trust in the beneficiary about the objectivity of the information they furnish.

We also believe it would be helpful if CMS would follow the IRS' lead and supply public libraries with hard-copy Medicare literature on plans available in the area so that the individuals could take the information home and review in detail without undue time pressures. These materials need to be well designed and use graphics and other such tools to facilitate meaningful comparisons of key plan characteristics. Despite CMS' desire to rely on the web, many of the

beneficiaries it serves still do not have access to a computer. Some of those that do are not technically savvy or mentally coherent enough to use that computer effectively.

### **Proposals Relating to Enrollment of Beneficiaries Qualified for the Low-Income Subsidy**

NPAF recognizes that ACA mandates the changes CMS is proposing pertaining to: (1) the methodology for calculating the LIS benchmark premium, (2) the waiver of a *de minimis* monthly beneficiary premium for LIS-eligible individuals, (3) the prohibition against reassignment of LIS-eligible beneficiaries from plans that choose to waive *de minimis* premiums, and (4) the auto-assignment of other LIS beneficiaries to plans that are so waiving. We are supportive of the proposed regulatory changes.

PAF case managers have been called upon repeatedly to assist LIS-eligible beneficiaries who have been randomly reassigned to plans that are ill-suited to their needs. We appreciate the importance of minimizing reassignments to ensure continuity of drug coverage for this vulnerable population.

We would like to point out that despite the change designed to cut down on annual reassignments, there is still a crying need for a well-defined process for resolving problems that arise at the beginning of every plan year with LIS-eligible beneficiaries who are forced out of their current plan because of the plan's new premium level but who nonetheless are not properly auto-enrolled in another plan. Similar problems crop up through the plan year with individuals newly eligible for Medicare. The interplay between Social Security and CMS systems and the inordinate slowness of systems updates lies at the heart of many such problems.

Sometimes each agency points fingers at the other when a problem is brought to their attention. We urge CMS to develop a straight-forward process for addressing the enrollment of LIS-eligible individuals that fall through the reassignment crack or who become Medicare eligible in the middle of a plan year and to post that process on its website. Otherwise patients will continue to be told that they cannot fill prescriptions timely for the medicines they need because every pharmacy does not yet appear to be aware of the availability of coverage for anyone with best available evidence of LIS or dual eligible status. We have attached a case study in Exhibit 2 illustrating the LIS problem that the proposed improvements to the regulations still fails to address. CMS also must continue initiatives to educate pharmacists about the best available evidence requirements, to require plans to enforce such rules at their contract pharmacies, and to strengthen its oversight plan and pharmacy compliance.

### **Proposals to Streamline Exception and Appeal Requests and Other Forms**

Pursuant to ACA § 3312, CMS is proposing to require every MA-PD and freestanding prescription drug plans (PDPs) to use a single, uniform exceptions and appeals process that includes procedures for accepting requests for coverage determinations and redeterminations orally, in writing or electronically through a secure website. CMS is also proposing to mandate the use of a standardized request form or forms for coverage determinations and redeterminations. Finally, CMS envisions working with NCPDP to develop and standardize the use of codes that will prompt a Part D network pharmacist to print or provide a point-of-sale notice explaining why a prescription cannot be filled and detailing the processes available to the

beneficiary for addressing the situation. We, along with other patient advocate groups, have been lobbying for such changes for years and we are delighted to see the standardization process finally get under way.

The PAF case managers recommend including the following elements in the contemplated standardized form that would be completed by the patient:

- Patient demographics
- Plan name and ID number
- Patient contact information
- Identification of the brand or generic drug being requested
- Explanation of the reason(s) why a patient must take the drug at issue – perhaps a drop-down menu or a check the box format could be appropriate here
- Inquiries about whether the patient has taken any drug at issue before and, if so, what were the results and about whether the patient requesting a brand drug has tried available generics and, if so, what were the results

We also urge the development of a separate form for medical information that would be completed by the treating physician. The patient is not likely to have the medical documentation needed to support decision-making on the exception or appeal requests. Of course, if this approach is adopted, some system for linking the patient and physician forms will be crucial to efficient processing.

When exception or appeal requests are submitted electronically, patients and their physicians should be able to print out a “receipt.” Receipts should be mailed when an oral request is submitted and logged into the electronic form by the plan sponsor. Ideally, we would like to see plan sponsors simultaneously log exception and appeal requests with Medicare in a way that would permit patients and physicians to track request processing through Medicare.gov or a secure CMS website.

CMS also has proposed changes to the procedures for filing complaints and documenting their resolution. If the proposals are finalized, plans will be required to record how complaints were resolved, not the mere fact of their resolution. We note that CMS is currently contemplating using a drop down checklist for this purpose. PAF case managers have years of experience in documenting the resolution of access problems. Based on their experiences, we encourage CMS to include the option of supplementing checklist entries with information supplied in a free-form text box. The same suggestion applies to the model electronic complaint form that beneficiaries will be able to access at Medicare.gov and on the website for the Medicare Beneficiary Ombudsman. NPAF commends the proposal that all complaints be linked from plan websites to forms on Medicare.gov. We are firm believers in the value of considering responses to beneficiary and physician complaints when plans are rated because we believe doing so will encourage plans to develop processes to avoid repeated complaints about the same or similar issues. We also see value from a regulatory planning perspective in CMS having the ability to assess systematically the effective and the not-so-effective resolution of common complaints.

## **Proposal for Short-Cycle Dispensing in Long Term Care**

Although NPAF supports efforts to rein in waste and reduce costs to the Medicare program and to the beneficiaries responsible for a portion of Medicare-allowable charges, we believe CMS has more work to do before it will be in a position to develop a viable short-cycle dispensing rule that adequately addresses the multiplicity of considerations we see associated with such a radical change in standard pharmacy practice.

We recognize that a shorter dispensing cycle for patients residing in long term care (LTC) facilities should help avoid the waste that occurs when 30-day prescriptions are dispensed to patients subject to frequent changes in prescription orders because of drug intolerances and/or changing medical conditions or to patients who die or are otherwise discharged from a LTC facility before the 30-day supply is exhausted. We also realize that requiring returns of unused drugs for credit in those states that permit the practice has the potential to reduce costs as well so long as restocking fees on short-cycle returns do not outpace the ingredient cost savings. If CMS finalizes a proposal permitting such returns, we ask that it ensure that the final regulations expressly state that beneficiaries are to share in any refund resulting from the return in proportion to the amount of the total cost for the returned drugs covered by their cost-sharing contribution.

We suspect that the dispensing fees associated with short-cycle dispensing are likely to be higher than those currently applicable when 30-day supplies are provided. Given this reality, it will be important for CMS to include in any rule finalizing such a change in pharmacy practice, provisions designed to ensure that short-cycle prescribing is required only in situations where the net effect of the ingredient cost savings and the dispense fee increases will result in overall cost saving. Our reading of the Proposed Rule suggests that the permanent and temporary exceptions to 7-day dispensing CMS has proposed – for mental health facilities, Indian Health facilities and rural pharmacies – are based primarily on operational considerations and, in the case of mental health facilities, clinical concerns. There is no provision in the proposal that takes into account the possibility that net “cost savings” associated with the proposed dispensing cycle change could be negative when patients are taking low-cost generic medications. We encourage CMS to study this issue because we understand that such drugs make up a substantial portion of drugs taken by LTC residents. We suspect CMS may need to consider a carve-out for low-cost products before it moves forward with any regulation requiring a dispensing cycle change.

Several other issues also raise questions about whether CMS has developed the short-cycle dispensing concept sufficiently to justify the current proposal. For example, we are concerned about the impact of the Proposed Rule on LTC residents who are in a custodial stay that is not covered under Medicare skilled nursing benefit and who, because they are not dual eligible, receive their prescription drug coverage through Medicaid. We understand that the short-dispensing cycle rule change would only be applicable to Medicare but we suspect that operational considerations would lead to most, if not all, LTC pharmacies adopting the 7-day cycle across the board. We can easily envision situations where even the minimal Medicaid co-payment on a prescription becomes a financial burden on such patients if the states are allowed to impose the co-pay obligations currently in effect on each 7-day fill. In addition, we wonder how the Proposed Rule would affect the presentation of co-pay information for MA plans and PDPs on the CMS Plan Finder and how it would complicate the comparison of drug plan options

available to beneficiaries. As we have discussed above, better educating beneficiaries about how to carry out appropriate plan comparisons is already a recognized need. We also urge CMS to incorporate plans' handling of complaints.

### **Other Proposals of Interest**

*Medical Necessity Reviews* – We applaud the proposal to require Part C and Part D plans to make physicians or other appropriate medical professionals responsible for reviewing medical necessity determinations

*Definition of Pharmacist* – We were disturbed to learn that some plans have been using pharmacists that are not licensed in the United States to make clinical judgments about Part D benefits. We are fully in agreement with the proposal to re-define pharmacist to require U.S. licensure. We would like to see the addition of a regulation requiring the re-evaluation of any coverage decision made by an unlicensed pharmacist and the refund to beneficiaries of costs they incurred because of any decisions that are reversed on review.

*Income Related Monthly Adjustment Amount (IRMAA)* – We foresee enrollment “glitches” similar to those that plague LIS-eligible beneficiaries who are inadvertently dropped from one plan but not correctly auto-enrolled in the next. Undoubtedly, some high-income beneficiaries will face disenrollment because of miscommunications that result because prescription drug premiums are paid to their chosen plan and IRMMAs to CMS. We encourage CMS to develop an expeditious, straight-forward process for resolving such problems and to publicize that process on Medicare.gov.

*Grace Periods for Resolving Premium Payment Defaults* – We believe beneficiaries should be notified of premium payment defaults and given a grace period to resolve deficiencies before disenrollment. We would favor a three month time frame. We also support permitting reinstatement of disenrolled beneficiaries who can demonstrate a good faith cause for their failure to submit premium payments timely. Provisions for payment plans in such situations would be an appropriate requirement, especially for beneficiaries living on fixed incomes or for individuals who incorrectly thought premiums were being deducted directly from their Social Security checks. We suspect many of these beneficiaries would have difficulty paying premiums for two or three months at one time.

\* \* \* \* \*

Thank you for the opportunity to comment on the proposals for improving the rules governing the operation of MA plans and freestanding prescription drug plans. From the perspective of the beneficiaries to whom we strive to give voice, we found a great deal to like in the Proposed Rule. We have tried to provide constructive suggestions in response to some of the questions posed in the preamble to the Proposed Rule and where we had concerns about the direction or adequacy of the proposal.

We would be pleased to respond to any questions about our recommendations. We also would welcome the opportunity to have you tour PAF's facilities in Newport News, Virginia, where

you can observe a live demonstration of the work put into the resolution of patient access issues by the PAF case managers – work that provides the foundational experience and perspective underlying our comments and recommendations.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Nancy Davenport-Ennis". The signature is written in a cursive style with a large initial "N".

Nancy Davenport-Ennis  
Chief Executive Officer and President

## EXHIBIT 1

**Gender:** Female  
**Age:** 43  
**Insurance:** Medicare  
**Ethnicity:** Caucasian  
**City/State:** Anderson, SC  
**Diagnosis:** Stage IV Bone Cancer

**Issue:** Medicare inaccurately disenrolled the patient from Parts A and B resulting in the patient's inability to enroll in a clinical trial until the Medicare system was updated. Medicare would not update its system in a timely fashion.

**Problem:** The patient had regular Medicare Parts A and B. On March 31<sup>st</sup> she was convinced by a door to door salesman to enroll in Guardian HMO, which is a Medicare Advantage plan. The next day she decided to remain with regular Medicare and contacted Guardian to let them know of her decision. Guardian cancelled her enrollment before her effective date and considered her as never enrolling as an active member. Guardian transmitted notice of cancellation to Medicare so that the patient's A & B would be reinstated. Guardian received confirmation from Medicare that the cancellation notice was received. Medicare did not, however, update its system to reflect that the patient still had coverage under A & B. As a result of the delay in updating the system, the patient's coverage remained listed as enrolled with Guardian HMO. An update to the Medicare system was urgently needed since this was a Stage IV cancer patient who had tried every type of treatment available with no positive results. Her doctor had informed her that her only option was to enroll in a clinical trial through MD Anderson in Texas and he referred her to this trial. However, MD Anderson would not schedule the patient's initial consultation until the patient's information was updated in the Medicare system as they do not accept Guardian HMO. The patient had attempted to resolve this issue on her own for two weeks before contacting Patient Advocate Foundation for assistance.

**Resolution:** The Case Manager mediated between the patient, Medicare, Guardian, and MD Anderson via multiple conference calls that lasted a total of four hours. The Case Manager obtained a letter from Guardian that explained that the patient was never considered an active member. The Case Manager conference called to Medicare along with a Guardian representative and the patient to explain that it was imperative to have the Medicare system updated so that the patient could begin treatment through the clinical trial. The Case Manager spoke to two Medicare representatives and two Medicare supervisors all of whom refused to provide assistance. The supervisors stated that it could take up to 45 days for the system to be updated and that they had not received a notice of disenrollment from Guardian. The Guardian representative informed the supervisors that the notice had been sent to Medicare twice and that

she had received confirmation from Medicare acknowledging that the patient was never enrolled. The supervisors still refused to provide assistance. The Case Manager then conference called to MD Anderson with the Guardian representative and the patient in hopes that verbal confirmation from Guardian that the patient was never enrolled would be proof enough to allow the patient to be scheduled for the initial consultation. The supervisor at MD Anderson stated that they could not schedule the patient until the Medicare system reflected that the patient is currently enrolled with Parts A & B and needed to know if her coverage would be retro activated back to April 1<sup>st</sup> or if coverage would not begin until May 1<sup>st</sup>. The Case Manager asked if the patient could be seen as a self-pay patient and then have Medicare billed once the system is updated. The MD Anderson supervisor replied that they do not accept self-pay patients and that the cost of an initial consultation is \$21,855.00. The Case Manager then contacted the Medicare regional office and explained the patient's dilemma. The regional office provided the Case Manager with an official letter stating that the patient's coverage with Parts A & B would be retro activated back to April 1<sup>st</sup> and that their system would reflect this in 7-10 business days. The Case Manager then called MD Anderson again and faxed a copy of the official letter to the supervisor. The supervisor confirmed that the letter would serve as proof of the patient's coverage and that an initial consult would be scheduled. The patient was able to schedule the consultation and no longer delay enrollment in the trial. As a Stage IV patient who did not respond to other treatments and whose prognosis was terminal, resolution of this issue lifted quite a burden and gave her hope for prolonging her life.

PAF/53635-10

PAF Case Manager: Judith Storey

Referral: Lance Armstrong Foundation (Patient Advocate Group)

## EXHIBIT 2

**Gender:** Female  
**Age:** 57  
**Insurance:** Medicare  
**Ethnicity:** African American  
**State:** Hampton, Va.  
**Diagnosis:** Renal Failure  
**Treatment:** Dialysis and Medication

**Issue:** Patient was new to Medicare due to going into her fourth month of dialysis. Patient was not aware of the change from Medicaid to Medicare and went to her local pharmacy for her regular monthly medication refills. She was told that her Medicaid was no longer showing effective and referred to our foundation for help.

**Problem:** Patient was in renal failure and could not be without her medication. She contacted her case work at the local Department of Social Services. The works' records still reflected that the patient was eligible for Medicaid and did not reflect the patients 090107 Medicare effective date.

**Resolution:** The patient contacted me and I explained her payer changes to her. She had not been educated on the process and did not know to enroll into a Part D plan prior to 090107. She had not received any publications from Medicare. I enrolled her into the low-income subsidy and a Medicare Part D plan with Humana. We verified her Medicaid status and contacted the regional Medicare office. CMS was able to retroactive her Part D enrollment to 090107. I contracted her pharmacist, who was willing to dispense medication based on my efforts and the best available evidence rule.

PAF/93493-07

PAF Case Manager: Margie Griffin