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December 8, 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-4157-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 2013 and Other Proposed Changes; Considering Changes to the Conditions of Participation for Long Term Care Facilities," which was published in the *Federal Register* on October 11, 2011.<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 2010 (July 1, 2010 – June 30, 2011), PAF resolved 88,233 patient access cases and received more than four million additional inquiries from patients nationally. About 25% of the individuals receiving direct professional intervention from PAF case managers were Medicare beneficiaries with 69% of these beneficiaries living in annual household incomes of \$23,000 or less.

PAF operates a Co-pay Relief Program (CPR) under the auspices of OIG Advisory Opinion 04-15 and OIG Advisory Opinion (modification to 4-15 on 8/29/08) that provide direct financial assistance with co-payments for pharmaceutical products to insured patients who qualify medically and financially.

<sup>1</sup> 76 *Fed. Reg.* 63018 (Oct. 11, 2011).

Although CPR and case management are operated as separate PAF service divisions, they cross-refer when appropriate. In fiscal 2010, CPR furnished cost-sharing assistance with products covered under both Medicare Part B and Part D through 20 fully funded disease-specific funds. The program enrolled 13,848 individuals, nearly half of whom were over the age of 65. Of the \$31.2 million allocated to patients to help alleviate the financial burden of out-of-pocket drug costs, 58.61% was dispersed to individuals insured by Medicare.

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 and our case managers continue to assist individuals with plan selection and enrollment on a regular basis.

We are writing today again to applaud many of the program refinements detailed in the Proposed Rule. Regardless of whether the changes being put forward 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 patient-centric ways that value the needs of Medicare beneficiaries. For that, we thank you.

Our comments identify aspects of the Proposed Rule that we wholeheartedly support and endorse, provide substantive responses to several of the specific questions raised for comment, and include recommendations for modifying or expanding certain of the contemplated changes. We have organized our comments by topic to facilitate review.

#### **Proposal to Exclude Poor Performing Part D Plans**

The Proposed Rule would provide CMS with the express and explicit authority to terminate its contracts with sponsors of Medicare Advantage Prescription Drug Plans as well as freestanding Prescription Drug Plans (collectively, Part D Plans) that have failed to achieve at least a 3-star summary plan rating under the CMS 5-star plan rating system for a period of three consecutive contract years. Medicare Advantage Prescription Drug Plans receive annual star ratings in five domains related to their management of the medical benefit---staying healthy:

- screening tests and vaccines;
- managing chronic (long term) conditions;
- rating of health plan responsiveness and care;
- health plan members' complaints and appeals; and
- health plan telephone customers.

Medicare Advantage Prescription Drug Plans and freestanding Prescription Drug Plans receive annual star ratings in 4 domains related to their management of the pharmacy benefit—drug plan customer service; drug plan member complaints and Medicare audit findings; member experiences with the drug plan; and drug pricing and patient safety.

NPAF commends CMS for using its star rating system to reflect minimum standards of quality and service that Part D Plans must achieve to continue to provide Medicare Part D medical and pharmacy benefits to patients. As CMS highlights in the Proposed Rule, a summary plan rating of 3 stars is average and the proposed regulation would ensure that only those Part D plans capable of performing at an average or better level would be permitted to provide health care to beneficiaries.

NPAF recognizes that terminating Part D Plans based solely on those quality of care activities for which Part D Plans receive star ratings could negatively impact Part D Plan availability and beneficiary plan choice, particularly for cost sensitive beneficiaries, since Part D Plans with higher quality scores and star ratings tend

to have higher premiums. Nonetheless, NPAF agrees with CMS' proposal to permit it to terminate poor performing Part D Plans that have received a summary plan rating of less than 3 stars for 3 consecutive contract years. Three years should afford plan sponsors sufficient opportunity to digest receipt of a low star rating and to develop and implement effective corrective actions to improve performance and the corresponding star ratings to an acceptable level. While we realize that star rates alone are not complete measures of quality or value, we believe according Part D Plan sponsors full termination appeal rights under 42 C.F.R. § 423.642 *et seq.* should allow a full airing of countervailing patient care accomplishments and permit a fair, more nuanced final decision in the event CMS issues a termination notice based on consistently low star ratings. CMS must seek to inform and provide to beneficiaries a process that assures those displaced by the elimination process of their plans are provided an alternative plan available in their marketplace for enrollment.

### **Proposal to Establish Preferred Durable Medical Equipment (DME) Items and Supplies**

CMS is proposing to allow Medicare Advantage Prescription Drug Plans that now are required to cover DME items and supplies pursuant to Medicare Part B to limit coverage to certain preferred DME products or brands. In other words, the Proposed Rule would permit DME "formularies" similar to Part D drug formularies. While NPAF agrees that the use of such DME formularies may result in lower beneficiary cost-sharing obligations for certain preferred DME items and supplies because a formulary should allow Medicare Advantage Plans to negotiate substantial discounts and rebates for items and supplies accorded preferred status, NPAF is concerned that the use of such DME formularies could restrict patient access to certain DME items and supplies covered under traditional Medicare Part B and limit patient freedom of choice.

To ensure a proper balance between cost and access, CMS must incorporate safeguards around the use of DME formularies similar to those imposed by it on the establishment and operation of Part D drug formularies. For instance, CMS should mandate annual review and approval of DME formularies established by Medicare Advantage Plans by the Plans' respective Pharmacy and Therapeutics Committees as well as by CMS during the annual contracting process. In addition, a formal exceptions process for non-formulary DME items deemed medically necessary for a particular patient, similar to that employed for Part D drugs pursuant to 42 C.F.R. § 423.578, should be mandated for Medicare Advantage Plans using DME formularies. Lastly, patients should have the right to seek review of adverse determinations related to requested DME items or supplies by an independent review entity in a manner similar to that utilized for adverse determinations made by Part D Plans related to Part D drugs.

### **Proposal to Establish the Independence of Consulting Pharmacists in Long Term Care (LTC) Facilities**

In the Proposed Rule, CMS is exploring whether consultant pharmacists in LTC facilities should be independent from long term care pharmacies, pharmaceutical manufacturers and distributors. CMS has expressed concern that the intertwined financial relationships between consultant pharmacists, LTC pharmacies, pharmaceutical manufacturers and distributors may negatively impact medical decision-making, patient safety and quality of care. Particularly, CMS is concerned with the ability of consultant pharmacists to switch LTC patients' medications without regard to the cost structure of the patients' Part D Plan formularies, the functioning of drug utilization management programs or, most importantly, the best of interest of the patient. These concerns are reflective of issues raised and investigated by government enforcement authorities in several recently resolved False Claims Act cases.

NPAF shares CMS' concerns. The Medicare beneficiary/patient population residing in LTC facilities is especially vulnerable given that such patients often cannot advocate on their own behalf, sometimes do not have relatives or concerned caregivers to advocate for them and must look instead to their health care providers, including consultant pharmacists, to protect them. As such, we see requiring LTC consultant pharmacists to be free of interests that may conflict with or appear to conflict with their duty of care to LTC patients as a reasonable way to ensure that LTC facility residents receive the benefit of independent of clinical judgment and pharmacy care services focused on drug therapies that truly are in their best of interests.

## Other Proposals of Interest

Establishment of Daily Cost-Sharing Rate For Initial Fills. – We applaud the proposal to require Part D Plan sponsors to provide beneficiaries access to daily pro-rated cost-sharing rates for initial fills of prescriptions for less than 30-day supplies. This practice will allow patients to try a new medication for a short timeframe and discontinue a new therapy in the event the medication is not well tolerated or results in significant side effects with little waste both financially, to the patients and Part D Plan sponsors, and environmentally in terms of the disposal of unused medication. In addition, the provision of an initial fill of a new medication at a daily cost-sharing rate and in a quantity less than a 30-day supply will permit a patient to only purchase and pay for the initial day supply needed before he/she has an opportunity to order and receive an extended supply of the newly prescribed medication from his/her regular mail order pharmacy or to fill the prescription on the same schedule as his/her other maintenance medications, thus avoiding confusion as to the refill timing of multiple medications and possibly improving medication adherence.

Expansion of Part D Coverage. – Section 175 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), requires that Part D Plans cover benzodiazepines and barbiturates when used to treat epilepsy, cancer, or chronic mental health disorders on or after January 1, 2013. NPAF supported this statutory change when it was enacted. We know from patients seeking assistance from PAF that the lack of coverage for such drug therapies under Medicaid and Medicare Part D and ineffective coverage of such drug therapies for patients with other insurance coverage can be a substantial impediment to adherence and effective disease management. We are pleased to see CMS taking the regulatory steps necessary to implement Section 175 of MIPAA timely.

Extension of the Coverage Determination and Appeals Process to Disputes Involving the Coverage Gap Discount Program. – Although the Coverage Gap Discount Program will undoubtedly allow PAF to help more patients this year than last, it is clear there will be a continuing need for CPR even after the donut hole has been “closed” because many Medicare beneficiaries that do not qualify for the low-income subsidy still will be unable to afford the cash flow drain of a 25% co-insurance obligation under the ever-expanding TrOOP amount that separates the Part D initial cover limit and the beginning of the catastrophic benefit. We fully support the proposal extending the existing coverage determination and appeals process available to Medicare Part D beneficiaries to disputes involving the availability and amount of the point-of-service discount available under the Coverage

Gap Discount Program to beneficiaries who would otherwise face 100% co-insurance during the Part D donut hole. Beneficiaries, their representatives and advocates should be afforded an opportunity to pursue any amounts believed due to them under the Medicare Part D benefit, including the Coverage Gap Discount Program as outlined in ACA, and seek additional review by the independent review entity of determinations made by Part D Plan sponsors that amounts are not due under the Coverage Gap Discount Program.

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Thank you for the opportunity to comment on the proposals for improving the regulations governing the operation of Medicare Advantage 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. If we can be of assistance to CMS, please do not hesitate to contact us.

Respectfully submitted,



Nancy Davenport-Ennis  
Chief Executive Officer and President