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March 25, 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-3225-P: Medicare and Medicaid Programs; Patient Notification of Right to Access State Survey Agencies and Medicare Beneficiary Notification of the Right To Access Quality Improvement Organizations

Dear Dr. Berwick:

National Patient Advocate Foundation (NPAF) would like to thank you for the opportunity to comment on the Proposed Rule entitled “Patient Notification of Right to Access State Survey Agencies and Medicare Beneficiary Notification of the Right to Access Quality Improvement Organizations,” which was published in the *Federal Register* on February 2, 2011.¹ NPAF is a non-profit organization dedicated to improving access to healthcare services through both federal and state policy reform. Its 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 82,963 cases nationally and provided information to almost 4 million online contacts.

For over 15 years, NPAF has been an advocate for improving not only patient access to care but patient access to *quality* care. It is familiar with the important role quality improvement organizations (QIOs) are entrusted to play in responding to patient complaints, investigating allegations, and recommending action to improve quality of care for Medicare beneficiaries. NPAF’s companion organization, PAF, has served for 15 years as a patient advocate for patients throughout the United States. That expertise supports the recommendations that will be identified in this letter, and offers an alternative consideration regarding the supposition identified in the proposed rule that a contributor to the low volume of QIO beneficiary complaint reviews is that beneficiaries are unaware of their right to voice complaints to the QIO in their State.

¹ 76 Fed. Reg. 5755 (Feb. 2, 2011).

NPAF supports the expansion to a greater number of providers and suppliers of the requirement to inform Medicare beneficiaries of QIO services. Because of the shift in expenditure of Medicare funds by provider type, the current regulations that require only hospitals to inform beneficiaries who are served as an inpatient of QIOs' responsibility to improve the quality of care they receive has little impact and will likely have lesser impact in the future. A June 2010 Medicare Payment Advisory Committee (MedPAC) report found that a greater percentage of Medicare spending is now attributed to non-hospital providers². In 1999, Medicare expenditures totaled \$208 billion and hospital inpatient services accounted for 41% of those expenditures. By 2009, Medicare expenditures had risen to \$491 billion while the percentage of hospital inpatient expenditures decreased to 27%, although it was still the largest spending category.³ This trend indicating a decrease in the percentage of Medicare inpatient hospital expenditures is likely to continue as the percentage of hospitals offering outpatient services grows. In 1991, 92 percent of hospitals provided outpatient services while 94 percent did so in 2002.⁴ Clearly the resultant negative correlation between high Medicare dollar expenditure by provider and provider duty to inform beneficiaries of QIO patient complaint responsibilities frustrates efforts to improve quality of care for Medicare beneficiaries.

While NPAF applauds the Centers for Medicare & Medicaid Services' (CMS) efforts to expand the number of beneficiaries who will receive notification of QIO responsibility to investigate patient complaints, it suggests CMS reconsider the proposed list of Medicare certified providers and suppliers affected by this rule. Specifically, NPAF suggests CMS include ESRD clinics to compliment the scope of chronic disease providers as identified herein. While at first blush it may appear reasonable to exempt End Stage Renal Disease (ESRD) facilities because of their similar complaint process, the two different complaint systems will make opportunities to compare quality measures across providers possible for ambulatory surgical centers, hospices, hospitals, long term care facilities, home health agencies, comprehensive outpatient rehabilitation facilities, critical access hospitals, clinics and rehabilitation agencies, portable x-ray services and rural health clinics and federally qualified health centers while explicitly exempting ESRD facilities from this opportunity.

ESRD facilities will also not enjoy the robust quality data inherent to a comprehensive complaint monitoring system. This result is an unfortunate one as infection is a leading cause of morbidity and ranks second to cardiovascular disease as the leading cause of death in the chronic uremic patient on hemodialysis.⁵ This exclusion will also disproportionately affect African Americans as they comprise the greatest percentage of ESRD patients. African Americans have consistently suffered from a greater than 3.5-fold higher rate of treated ESRD than has the white population.⁶ Inclusion of the ESRD clinics will allow the data collected documenting quality issues to provide a platform for change in delivery of care likely to reduce adverse events and improve patient safety and outcomes.

Another important omission from the list of providers subject to the proposed regulations is outpatient rehabilitation facilities (ORFs). While the regulation text explains the rationale regarding the omission of ESRD facilities from its provisions, it is silent regarding the absence of ORFs from this listing. The omission is peculiar because while ORFs are omitted, comprehensive outpatient rehabilitation facilities are included. A 2007 MedPAC publication

² National Health Care and Medicare Spending. MedPAC June 2011

³ Ibid

⁴ Hospital Inpatient and Outpatient Services. MedPAC March 2004

⁵ CDC HHS Action Plan to Prevent Healthcare-Associated Infections: End-Stage Renal Disease Facilities

⁶ Am.J Kidney Dis. 1992 May; 19(5):397-410

which highlights the distribution of outpatient therapy Medicare spending by setting reveals spending was only 4% for CORFs and yet 14% for ORFs further confounding this omission.⁷

All providers subject to the new reporting requirement should give beneficiaries notice of the QIO responsibilities regarding complaints both at the time of admission as well as upon completion of treatment. Patients often are preoccupied with the impending treatment and healing process to fully comprehend the significance of the notice if it is provided to them only at the time of admission. The recently-released Institute of Medicine Health Literacy Research: Workshop Summary highlights a study that revealed that the average outpatient patient asks 1.5 questions from the time he or she arrives until departure- including questions about parking.⁸ Thus, the option that suggests QIO notice be given upon completion of treatment or discharge (in addition to the notification upon admission) only if the Medicare beneficiary has experienced an adverse event should not be favorably considered.

The role and expertise of QIOs should be considered when contemplating whether a contributor to the low volume of QIO beneficiary complaint reviews is that beneficiaries are unaware of their right to voice complaints to the QIO in their State. Section 1154(a)(14) of the Tax Equity and Fiscal Responsibility Act (TEFRA) defines an important role for QIOs. It allows for QIO review and resolution of a complaint if filed by an individual entitled to benefits for such services under Medicare or a person acting on the individual's behalf.⁹ Section 1152 of the Act defines the entities that can serve as QIOs and lists requisite staff composition. Essentially, QIOs must employ a sufficient number of doctors engaged in the practice of medicine or surgery in the area. The Omnibus Budget Reconciliation Act of 1986¹⁰ amended TEFRA to require each QIO board to have a consumer representative. Thus, there is no statutory or regulatory requirement for QIO staff to have expertise in the area of patient advocacy. Beneficiary complaint volume will likely increase if the beneficiaries are informed by consumer representatives skilled in patient advocacy or by actual patient advocates.

The QIO model has likely contributed to the challenges identified by federal and non-federal entities in QIO ability to adequately address beneficiary concerns in its efforts to improve the quality of care received by Medicare beneficiaries. In May 2007, the Office of Inspector General reviewed the extent to which QIOs identify quality of care concerns through medical record review. The OIG report reviewed QIO findings over a three-year period and found that over eighty percent of confirmed quality concerns were relegated to one of the two least serious classifications- "care could have reasonably expected to be better" or "care failed to follow general accepted guidelines or usual practice."¹¹ Less than two percent of corrective actions were assigned to the two most severe actions.¹² An Institute of Medicine (IOM) review of the QIO program found that QIOs perform far less than expected beneficiary complaint reviews.¹³ The report recommends that "Congress and CMS should improve QIO governance by requiring (1) broader representation of all stakeholders on QIO boards, including more beneficiaries and consumers with the requisite training and executive-level representatives of providers;"¹⁴ Another recommendation designed to address QIO challenges in responding to beneficiary

⁷ Outpatient Therapy Services Payment System. MedPAC October 2007

⁸ IOM (Institute of Medicine). 2011. *Innovations in Health Literacy Research: Workshop Summary*. Washington, DC: The National Academies Press.

⁹ Pub. L. 97-248

¹⁰ Pub. Law 99-509

¹¹ Quality Concerns Identified through Quality Improvement Organization Medical Records Review Department of Health and Human Services Office of Inspector General. May 2007

¹² Ibid

¹³ Institute of Medicine: Medicare's Quality Improvement Organization Program. Washington (DC) National Academies Press. 2006

¹⁴ Ibid.

complaints advised, “Congress and CMS should develop mechanisms other than those already in place to better manage complaints and appeals of Medicare beneficiaries, as well as other case reviews.”¹⁵

NPAF recognizes the special expertise necessary to competently address patient concerns. As noted above, its comments are informed by the 15 years of experience PAF has gained providing patient advocacy services for patients throughout the United States. While QIOs have the statutory authority to assist CMS efforts to promote quality of care for Medicare beneficiaries, CMS has an important role in assuring QIOs comply with Statement of Work (SOW) requirements. CMS identified a core priority of QIOs to be “protecting beneficiaries by expeditiously addressing individual complaints, such as beneficiary complaints.”¹⁶ The first national theme identified in the 9th SOW was that of beneficiary protection.

NPAF recommends CMS consider the unique expertise patient advocacy organizations have and encourage QIOs to contract with them when implementing beneficiary protection activities identified in the 9th SOW. The QIO challenge in adequately performing this role is likely a greater contributor to the low volume of QIO beneficiary complaint reviews than is the fact that beneficiaries are unaware of their right to voice complaints to the QIO in their State. Patient advocacy organizations have garnered the trust of beneficiaries over time and it is that capital of trust that patient advocacy groups can expend to enable patients to recognize the value and importance of complaint submission. Simply educating beneficiaries of the QIO role will likely not significantly improve the quantity, nor more important, the caliber of patient complaints, an important component in efforts to improve the quality of care delivered to Medicare patients.

NPAF thanks you for your consideration of the above comments.

Sincerely,



Nancy Davenport-Ennis
Chief Executive Officer and President

¹⁵ Ibid.

¹⁶ Fact Sheet: CMS Awards Contracts for Quality Improvement Organizations 9th Statement of Work. 2008 CMS