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May 31, 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: **Medicaid Program; Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center - CMS -1345-NC2**

Dear Dr. Berwick:

The National Patient Advocate Foundation (NPAF) thanks you for the opportunity to provide comments on possible waivers of the application of the Physician Self-Referral Law, the Federal anti-kickback statute, and certain civil monetary penalties (CMPs) law provisions to specified financial arrangements involving accountable care organizations (ACOs) under the Medicare Shared Savings Program. ACOs are a new category of Medicare provider designed to provide high-quality coordinated care to patients. The rule and the other ACO rules have the potential to positively transform the delivery of quality healthcare services to Medicare fee-for-service patients. It will likely serve as a model for commercial insurers interested in coordinating care and will thereby ultimately impact a greater number of patients. NPAF is pleased to submit comments on a rule that holds such potential for patients.

NPAF is a non-profit organization dedicated to improving patient 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. While other commenters may find responding to a patient-centric rule to represent a new paradigm, NPAF has a fifteen year history of serving as the trusted patient voice. 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 2010, PAF resolved 82,963 cases nationally and provided information to almost 4 million online contacts. PAF's Patient Data Analysis Report, which will be described in greater detail later, provides detailed analyses of these cases.

NPAF understands that the intent of the rule is to assure application of fraud and abuse laws do not unduly impede development of beneficial ACOs while also ensuring that ACO arrangements are not misused for fraudulent purposes that may harm patients. NPAF comments are clearly aligned with that intent and the following comments offer recommendations on how the Centers for Medicare and Medicaid Services and the Office of Inspector General might collaborate to assure the resultant rule is in the best interest of the patient.

The Physician Self-Referral Law, the anti-kickback statute, and the civil monetary penalty (CMP) provision addressing hospital payments to physicians offer strong consumer protections. They protect against fraud, improper referral payments, unnecessary utilization as well as underutilization. Each of these laws and their relationship to ACO formation as well as implementation will be addressed separately below.

### **Physician Self-Referral Law**

Section 1877 of the Social Security Act<sup>1</sup>, referred to as the “Physician Self-Referral Law” generally prohibits physicians from making referrals for Medicare “designated health services” including hospital services, to entities with which they or immediate family members have a financial interest. Essentially, the law seeks to assure physician clinical judgment is not unduly influenced by potential financial gain. The impetus for the passage of the Physician Self-Referral Law is often referenced as being primarily economic, yet health consumer protection is certainly the overarching reason for the law’s existence.

Around the time of passage of the law, there was clear evidence that physician ownership of entities performing certain services directly impacted referral patterns. A May 1989 Office of Inspector General (OIG) report found that patients of referring physicians who owned or invested in independent clinical laboratories received 45 percent more laboratory services than all Medicare patients in general.<sup>2</sup> This finding illuminated a possible trend when coupled with a statement by the former CMS Administrator referenced in the same study that since the introduction of the hospital inpatient prospective payment system, inpatient hospital costs had grown at a rate of 6 percent per year, while physician costs have grown at a rate of fifteen percent.<sup>3</sup> A Florida Cost Containment Board study found that doctor-owned clinical laboratories, diagnostic imaging centers, and physical therapy and rehabilitation centers performed more procedures on a per-patient basis and charged higher prices than non-doctor-affiliated facilities.<sup>4</sup> Another study on physician referral pattern differences also focused on Florida doctors. The General Accounting Office analyzed diagnostic imaging services of 17,900 Florida physicians and revealed those physicians with a financial interest in the joint venture imaging services had higher referral rates for almost all types of imaging services other physicians. For example, owners of joint ventures ordered 54 percent more magnetic resonance imaging scans. Another startling finding was that doctors with imaging services in their own offices ordered imaging services more frequently than those who referred patients to outside services.<sup>5</sup>

The first CMS proposed rule implementing the Physician Self-Referral Law succinctly summarizes the concerns associated with physician self-referrals as, “Having a financial interest in an entity that furnishes [health care] services can affect a physician’s decision about what medical care to furnish a patient and who should furnish the care.”<sup>6</sup> While self-referrals raise important financial issues, the care rendered to patients is, and should be, of paramount concern.

As noted above, ACOs are designed to provide high-quality coordinated care to patients and therefore hold tremendous promise for patients. However, that coordination coupled with the financial interest inherent to the Medicare Shared Savings Program may place ACO providers at risk of violating the Physician Self-Referral Law. While NPAF appreciates and respects the law’s intent to protect patients by assuring medical decisions are not influenced by potential financial gain, a balance between

<sup>1</sup> 42 U.S.C. 1395nn

<sup>2</sup> Office of Inspector General, “*Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress*” May 1989

<sup>3</sup> Testimony of William L. Roper, M.D. before the Subcommittee on Health, Committee on Ways and Means, U.S. House of Representatives, September 29, 1988.

<sup>4</sup> State of Florida Cost Containment Board, “*Joint Ventures among Health Care Providers in Florida*”

<sup>5</sup> General Accounting Office, “*Medicare:Referrals to Physician-Owned Imaging Facilities Warrant HCFA Scrutiny*” October 1994

<sup>6</sup> 63 FR 1659

patient/consumer protections and the promise that ACOs hold for patients must be carefully considered. After considerable deliberation, NPAF recommends that the proposed waiver of the physician self-referral law to financial distributions of shared savings within the ACO and distribution of savings outside the ACO for activities necessary for and directly related to ACO Shared Savings Program participation be included in the final rule. However, to assure these waivers, particularly the second one, are not abused, OIG should be charged with publishing ACO Physician Self-Referral Waiver Safe Harbor notices and conduct random audits of ACOs to assure the shared savings distributions do not result in under or overutilization of services rendered to patients.

As mentioned, ACOs offer great promise for patients to receive high quality care. It is likely the savings will be realized by patients in the form of lower co-pays. The greater the number of ACOs in existence, the greater the potential will be for patients to enroll in them and avail themselves of their benefits. To increase interest in ACO formation and address the start-up financial challenges providers might encounter, NPAF recommends CMS and OIG consider the Physician Self-Referral waiver be extended to ACO formation. Once again, considerable governmental oversight would be necessary to assure actual ACO formation or that the parties used their best efforts in such formation.

### **Anti-Kickback Statute**

The anti-kickback statute makes criminal offers, payments or solicitations to induce or reward the referral of business reimbursable under any of the Federal health programs, including Medicare.<sup>7</sup> Therefore, providers interested in participating in the Medicare Shared Savings Program may find their financial arrangements created by the distribution of the shared savings run afoul of this law. Like the Physician Self-Referral law, its intent is to protect the healthcare consumer by preventing the corrupting influence of money on health care decisions. The proposed rule essentially offers a waiver for any financial relationship between or among the ACO, ACO providers and suppliers, ACO participants only if the relationship implicates the Physician Self-Referral Law and fits squarely within an exception. The rule notes its desire in defining these waivers was to minimize the burdens on entities establishing ACOs.

NPAF concurs with the waivers and offers the following suggestion to further OIG and CMS' desire to minimize ACO formation burden. The three years of Medicare Shared Savings program participation will likely not yield any cost savings for sophisticated technological construction. Rather, they may jeopardize future savings. To mitigate against this inevitable outcome and to encourage ACOs to continue to strive for the down-stream benefits that will result from such investments, NPAF recommends the waiver be amended so that it is more expansive for relationships involving technological construction.

### **Civil Monetary Penalty**

The Civil Monetary Penalty (CMP) prohibits hospital payments to physicians to induce reduction or limitation of services, also called "gainsharing arrangements."<sup>8</sup> The proposed waiver would exempt distributions of shared savings received by an ACO participating in the Medicare Shared Savings Program as long as the payments were not made knowingly to induce the physician to reduce or limit *medically necessary* items or services and the hospital and physicians were ACO participants during the year the shared savings were earned by the ACO. Because the intent of the CMP relates directly to limitation of patient services, NPAF concurs with the restricted scope of the waiver to only ACO participants. We strongly suggest waiver expansion suggestions be considered in light of the strong patient protection offered by CMPs.

In summary, NPAF encourages both CMS and OIG to consider not merely the aforementioned laws but the intent of the laws to protect healthcare consumers when reviewing the many comment letters. A

<sup>7</sup> 42 U.S.C. 1320a-7b(b)

<sup>8</sup> 42 U.S.C. U.S.C. 1320a-7a(b)(1) and (2)

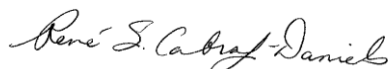
greater level of attention and consideration should be afforded patient advocacy groups which represent the very population these laws protect. Both agencies should also avail themselves of the considerable expertise of patient advocacy groups and integrate them into Medicare Shared Savings Program implementation.

NPAF thanks you for the opportunity to comment on this rule. As noted above, this rule is an important one as it has the potential to positively transform the delivery of quality healthcare services to Medicare fee-for-service patients if many of the issues defined herein are appropriately addressed. We would be pleased to respond to any questions about our recommendations that may arise in the future. We are also available to discuss, in greater detail, our suggestions regarding a role for the nonprofit community in the implementation of the rule.

Respectfully submitted,



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