June 6, 2011

Donald Berwick, M.D., M.P.P.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1345-NC2
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave. S.W.
Washington, DC 20201

Daniel Levinson, J.D.
Office of the Inspector General
Department of Health and Human Services
Attention: CMS-1345-NC2
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave. S.W.
Washington, DC 20201

Submitted electronically

RE: File Code CMS-1345-NC2 Medicare Program Waiver Designs in Connection with the Medicare Shared Savings Program and Innovation Center

Dear Dr. Berwick and Mr. Levinson:

On behalf of the over 78,000 member physical therapists, physical therapists assistants, and students of physical therapy of the American Physical Therapy Association (APTA), I would like to submit the following comments regarding the Waiver Designs in Connection with Medicare Shared Savings Program and Innovation Center notice with comment period published in the Federal Register on April 7, 2011. Physical therapists are very committed to improving the quality of health care and stand ready to participate in the innovative health care delivery models mandated under the Affordable Care Act (ACA), such as accountable care organizations (ACOs).

Physical therapists practice in a wide variety of inpatient and outpatient settings, including hospitals, skilled nursing facilities, home health agencies, rehabilitation agencies, physical therapist private practice offices, physician offices, and schools. As a large percentage of our members practice in small private practices and rehabilitation agencies, we believe that it is imperative that the Medicare Shared Savings Program (MSSP) is structured in a manner that ensures high quality care, preserves patient freedom of choice, and does not compromise the sustainability of small, independent practices.
In the notice with comment period, the Centers for Medicare & Medicaid Services (CMS) and the Department of Health Human Services’ (HHS) Office of the Inspector General (OIG) state that they seek to address application of the fraud and abuse laws to ACOs formed in connection with the MSSP so that the laws do not unduly impede development of beneficial ACOs, while ensuring that ACO arrangements are not misused for fraudulent or abusive purposes that harm patients of Federal health care programs. APTA shares the same aim and is deeply concerned that broad waivers to the federal physician self-referral law, anti-kickback statute, and gainsharing civil monetary penalty provisions for the formation of ACOs may pose unintended, negative consequences.

In the scope of the proposed waivers, the notice states the Secretary [of HHS] would waive application of the physician self-referral law to distributions of shared savings received by an ACO from CMS under the MSSP:

I. To or among ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or

II. For activities necessary for and directly related to the ACO’s participation in and operations under the MSSP.

Secondly, the Secretary [of HHS] would waive application of the anti-kickback statute for two scenarios:

I. Distributions of shared savings received by an ACO from CMS under the MSSP.

II. Any financial relationship between or among the ACO, ACO participants, and ACO providers/suppliers necessary for and directly related to the ACO’s participation in and operations under the MSSP that implicates the physician self-referral law and fully complies with an exception.

In regards to prohibition on hospital payments to physicians to induce reduction or limitation of services, the Secretary [of HHS] would waive application of the gainsharing CMP in two scenarios:

I. Distributions of shared savings received by an ACO from CMS under the MSSP in circumstances where the distributions are made from a hospital to a physician provided that the payments are not made knowingly to induce the physician to reduce or limit medically necessary items or services; and the hospital and physician are ACO participants or ACO providers/suppliers, or were during the year in which the shared savings were earned by the ACO.

II. Any financial relationship between or among the ACO, its participants, and its providers/suppliers necessary for and directly related to the ACO’s participation in and operations under the MSSP that implicates the physician self-referral law and fully complies with an exception.

While we recognize the need to grant waivers to enable ACO arrangements that coordinate care, improve quality and reduce unnecessary costs, it is important to ensure that these arrangements do not pose a risk of program or patient abuse. Section 1899 (f) of the Social Security Act (SSA) states that the Secretary shall grant waivers only “as may be necessary to carry out” the Program. We believe that CMS and OIG have proposed overly broad waivers to the anti-kickback statute, the physician self-referral law, and the gainsharing civil monetary penalty provisions that could potentially result in abusive financial arrangements that may skew incentives. Section 1877(b)(4)
of the SSA has always required that a permanent regulatory exception to the physician self-referral law be established only when it is clear that the exception can pose “no risk of program or patient abuse.” CMS and OIG should continue to apply this standard when developing permanent waivers.

When developing waivers, we request that CMS/OIG consider the implications of federal fraud and abuse laws on ACOs in the following areas:

I. Eliminating conflicts of interest that arise when physicians refer ACO patients for ancillary services within the ACO that are wholly-owned by the physician or in which the physician has a substantial financial interest.

II. Restraining abusive formation of contractual partnerships between hospitals and physicians which may negatively affect small independent non-physician providers and suppliers.

III. Mitigating unfair treatment of providers operating outside of the ACO network.

IV. Restricting incentives to offer deep discounts, waive co-pays and/or deductibles, and to offer other inducements to ACO patients.

Conflicts of Interest and Physician Owned Services

The CMS/OIG notice states that the physician self-referral law, anti-kickback statute and gainsharing civil monetary penalty provisions addressing hospital payments to physicians to reduce or limit services are important tools to protect patients and the Federal health care programs from fraud, improper referral payments, unnecessary utilization, underutilization and other harms. However, the federal agencies note that these laws may impede the development of some of the integrated-care models envisioned by the MSSP. Thus, §1899(f) of the SSA authorizes the Secretary of HHS to waive these, and certain other laws, as necessary to carry out the MSSP.

While we understand the rationale for needing to reexamine the applicability of these laws to ACOs established under the MSSP and CMMI, we strongly urge the Agencies to establish bright line safeguards that ensure a fair balance between encouragement of independent physical therapists and other non-physician provider involvement and prohibiting the proliferation of physician-owned physical therapy services that may incentivize physicians to exclude certain classes of providers and/or suppliers from participating in ACOs. APTA strongly believes that such exclusions would seriously compromise patient freedom of choice and access to quality care.

APTA strongly believes that the decision to include physical therapists and other non-physician providers as ACO participants should not be clouded by conflicts of interests and financial motivations. A prevailing mandate of §3022 of the ACA is that the MSSP program redesign care processes in a manner that promotes high quality and efficient service delivery. Therefore, we believe it is essential that the CMS/OIG carefully craft safeguards to the fraud and abuse laws with this goal in mind.

One of the biggest loopholes that results in abusive financial arrangements that are created solely for profit without regard to the best interest of the Medicare beneficiary is the in-office ancillary
services (IOAS) exception to the physician self-referral (Stark II) law. In the preamble to the 2008 Medicare Physician Fee Schedule proposed rule¹, CMS stated that, “In response to [Stark] Phase II, [the Agency] received hundreds of letters from physical therapists and occupational therapists stating that the in-office ancillary services exception encourages physicians to create physical and occupational therapy practices.”

Of particular concern to the profession of physical therapy are the increasing instances of physician-owned physical therapy service (POPTS) models appearing across the country. POPTS is a financial relationship in which a physician refers patients for physical therapy treatment and gains financially from the referral and it is generally created under the cloak of the IOAS to the Stark law. The IOAS exception allows patients of a sole practitioner or physician in a group practice to receive ancillary services in the same building and/or satellite offices in which the referring physician or his or her group practice furnishes medical services. This practice was designed to allow flexibility and convenience for the patient while receiving care. APTA contends that physical therapy services do not meet the criteria or stated purpose of the IOAS exception, and we are very concerned that the existing abusive behaviors under this exception will only be exacerbated in ACO models where physicians will have an even greater incentive to refer to physician-owned entities for physical therapy services delivered to Medicare beneficiaries.

In previous comments to CMS, APTA has strongly urged the Agency to remove physical therapy as a designated health service (DHS) permissible under the IOAS exception. Unfortunately, this revision has not been made, and for this reason, we believe that it is imperative that CMS/OIG restrict the ownership of physician-owned physical therapy services in ACOs formed under the MSSP and CMMI.

Physician ownership or interest in physical therapy, other specialty services and medical equipment often leads to overutilization and a decline in quality health care. This has been evidenced in OIG studies² and reports published by the Medicare Payment Advisory Commission (MedPAC)³. By restricting the physician’s ability to own or have a substantial financial interest in physical therapy and other ancillary services when providing services within an ACO, the Agencies would reduce a significant amount of programmatic abuse and overutilization of physical therapy services, and enhance the quality of patient care.

One fallacy behind the IOAS exception is that the services furnished under the exception are incident-to services; meaning that services are integral and necessary to the physician’s primary treatment and therefore require direct physician supervision. To the contrary, it is becoming commonplace that physician-owned physical therapy services are not furnished under the

¹ 72 FR 38181 (July 12, 2007).
Medicare incident-to provisions. Physicians are employing physical therapists who are obtaining their own individual provider numbers from Medicare, furnishing and billing for these services under their individual provider numbers, and then reassigning their benefits to the physician group practice for payment. Under this structure, there is little physician involvement during physical therapy treatment and the physical therapist treats the patient independent of physician supervision.

One argument that may be used in support of physician-owned physical therapy services in an ACO model is that services delivered in the physician’s office help to further the objective of clinical integration as discussed in the CMS MSSP proposed rule. We strongly disagree with this argument and would like to point out its flawed analysis.

Physical therapy services are recurring services and are administered over a prolonged period of time that requires the patient to return two to three times a week for therapy. In the course of this treatment, it is very rare that the patient is seen by the physician. Generally, the physical therapist develops the plan of care and consults with the physician for their input. After consultation, the physical therapist proceeds with the plan of care and the physician may, at their discretion, check on the status and progress of the patient on a periodic basis. Therefore, we contend, based on the general model of physical therapy treatment, that it is no more convenient for the patient to receive physical therapy services in the physician’s office than it is for the physician to refer the patient to an independent physical therapy clinic in which the physician has no financial ties.

Thus, physical therapy services can be effectively delivered independent of the physician and these services are not needed at the time of the physician visit to determine the patient’s diagnosis or the plan of care. As illustrated above, there is no prevailing quality of care need or added patient convenience realized by including physical therapy as a DHS under the IOAS exception. Therefore, it is evident that the IOAS exception should be significantly narrowed and closely monitored for purposes of the ACO model.

**Impact of Hospital/Physician Contractual Partnerships**

In § 3022 of the ACA and throughout the MSSP proposed rule, the formation and success of the ACO is said to be predominantly dependent upon the partnership of hospitals and physicians. While we understand the rationale for the focus on these two categories of Medicare providers and suppliers, APTA also recognizes that hospitals and physicians alone cannot meet all of the goals of the MSSP program for the various Medicare patient populations throughout the country. In order to be truly successful, ACOs will require the collective effort of hospital systems, physicians, non-physician providers and rural health care providers.

**Therefore, we strongly urge CMS and OIG to monitor the negative effect hospital and physician market dominance will have, especially on small, independent non-physician providers such as physical therapists in private practice.** One potential concern we have with the ACO models is that a hospital may choose a larger physician group practice that provides physical therapy services to participate in the ACO over a smaller specialized practice, such as a physical therapist private practice. This decision may be based on the larger physician group’s

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4 76 FR 19528 (April 7, 2011).
importance to the hospital as a referral source. Unlike physicians, physical therapists generally do not function as a primary referral source to the hospital. As a result, certain classes of providers, such as small physical therapist private practices, could be excluded from ACO participation, and we believe that such exclusions could potentially impact quality of care.

Also, as a consequence of these joint ventures, hospitals and physicians may place undue pressure on non-physician providers such as physical therapists to enter into questionable contractual arrangements that implicate the anti-kickback statute in order to participate in ACOs. These contractual agreements may include significantly lowering the proportion of shared savings distributed to non-physician providers and compensation arrangements cloaked in the guise of rental or personal services agreements. We believe this issue also warrants scrutiny and the establishment of the appropriate safeguards under the anti-kickback statute, physician self-referral laws and civil monetary penalty provisions.

**Unfair Treatment of ACO Non-Participating Providers**

With these waivers, CMS and OIG state that they intend to protect financial relationships involving the distribution of shared savings outside the ACO, but only if the distribution outside the ACO relates closely to the requirements for an ACO, including achieving the quality and savings goals of the MSSP. CMS and OIG do not intend to protect distributions of shared savings dollars to referring physicians outside the ACO, unless those referring physicians are being compensated (using shared savings) for activities necessary for and directly related to the ACO’s participation in and operations under the MSSP. Other financial relationships outside the ACO would need to meet an existing exception under the physician self-referral law (e.g. the fair market value, personal services, or indirect compensation) or safe harbor under the anti-kickback statute.

APTA applauds CMS/OIG for the inclusion of these proposed provisions within the waiver notice. As stated earlier, the ACO model may have unintended negative consequences that implicate the fraud and abuse laws. It is important to ensure that ACOs do not pose serious risk to the viability of other providers that do not participate in an ACO.

APTA believes the existence of these outside providers and suppliers is critical to preserve access to high quality care and freedom of patient choice. **We strongly urge CMS/OIG to ensure that providers and suppliers who are not participating within the ACO are not unfairly marginalized from treating Medicare patients because of patient assignment to an ACO and that incentives to impede referrals outside of the ACO are mitigated. In addition, we recommend that CMS/OIG periodically conduct an analysis of the volume of referrals outside of the ACO to detect aberrant referral patterns and unfair business practices.**

**Incentives to Offer Discounts, Waive Co-pays and Offer Inducements to ACO Patients**

As defined in the Social Security Act (SSA), remuneration does not include any reduction or waiver of a Medicare or State health care program beneficiary’s obligation to pay coinsurance or deductible amounts as long as the coinsurance or deductible amounts are owed to a hospital for

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5 Social Security Act §1128A
42 U.S.C §1320a-7(b).
inpatient hospital services for which Medicare pays under the prospective payment system (the hospital must comply with enumerated standards under the anti-kickback safe harbor provisions), or the coinsurance or deductible amounts are owed by an individual who qualifies for subsidized services under a provision of the Public Health Services Act.

The Act\textsuperscript{6} also states that remuneration does not include the waiver of coinsurance and deductible amounts by a physician, if the waiver is not offered as part of any advertisement or solicitation; the physician does not routinely waive coinsurance or deductible amounts; and the physician waives coinsurance and deductibles after determining in good faith that the individual is in financial need or failure by the physician to collect coinsurance or deductible amounts after making reasonable collection efforts.

As ACOs form and physicians and hospitals explore creative methods to encourage patients to stay within the ACO network for their Medicare services, it may be all too convenient for ACOs to employ these safe harbors to the anti-kickback statute in an abusive manner. Therefore, APTA requests that CMS/OIG ensure that ACOs are prohibited from waiving co-pays, giving deep discounts, or offering other incentives (i.e. free transportation and gym memberships) to ACO patients in order to incentivize them to receive services within the ACO.

In addition, APTA requests that the Agencies institute a system where they continually (e.g. on a yearly basis) assess the compliance of ACOs participating in the MSSP with the physician self-referral law, anti-kickback statute, and gainsharing civil monetary penalty provisions. We also request that the Agencies provide guidance to providers, suppliers and other stakeholders on methods in which the health care community can disclose or report potential violations of these anti-fraud and abuse laws.

In closing, APTA thanks CMS and OIG for the opportunity to provide input as the Agencies craft a legal and regulatory framework that balances the encouragement of ACOs and integrated care models with the establishment of appropriate safeguards to ensure that these models do not pose a serious risk to the integrity and sustainability of the US health care system. If you need additional information or have questions regarding our comments, please contact Roshunda Drummond-Dye at (703) 706-8547 or roshundadrummond-dye@apta.org.

Sincerely,

\[signature\]

R. Scott Ward, PT, Ph.D.
President

RSW: rdd

\textsuperscript{6} Id.