January 3, 2012

Marilyn Tavenner  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1439-IFC  
P.O. Box 8013  
Baltimore, MD 21244-8013

Daniel R. Levinson, J.D.  
Inspector General  
Office of the Inspector General  
Department of Health and Human Services  
Attention: CMS-1439-IFC  
P.O. Box 8013  
Baltimore, MD 21244-8013

Submitted electronically

RE: File code CMS-1439-IFC Medicare Program; Final Waivers in Connection With the Shared Savings Program

Dear Ms. Tavenner and Mr. Levinson:

On behalf of the over 82,000 member physical therapists, physical therapist assistants, and students of physical therapy of the American Physical Therapy Association (APTA), I would like to submit the following comments regarding the final waivers in connection with the Medicare Shared Savings Program (MSSP) interim final rule with comment period published in the Federal Register on November 2, 2011. We applaud CMS and the OIG for promulgating rules that seek to better align the Medicare Shared Savings Program with existing laws and regulations that govern fraud and abuse prohibitions, exceptions and safe harbors.

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, and schools. Physical therapists will be integral providers within accountable care organizations and other integrated models of care. Therefore, APTA stands ready to work with the federal agencies to craft waivers that are balanced in a manner that allows the needed flexibilities to form innovative models while providing necessary restrictions against fraudulent or abusive behavior.

The interim final rule sets forth waivers of certain provisions of the physician self-referral law, the federal anti-kickback statute, civil money penalties (CMP) law prohibiting hospital payments to physicians to reduce or limit services (gainsharing CMP), and the CMP law prohibiting inducements to beneficiaries (the Beneficiary Inducements CMP) as needed to implement the
MSSP and the Center for Medicare and Medicaid Innovation’s Advanced Payment Initiative. CMS and OIG state that the intent is to waive these laws so that they do not “unduly impede development of beneficial ACOs, while also ensuring that ACO arrangements are not misused for fraudulent or abusive purposes that harm patients or Federal health care programs.”

While APTA understands the rationale for needing to reexamine the applicability of these laws to ACOs established under the MSSP, we are greatly concerned that the waivers, in their current form, create unintended loopholes that will encourage fraudulent and unfair practices that will harm small health care providers and specialists such as physical therapists. Therefore, we strongly urge the Agencies to establish bright line safeguards that ensure a fair balance between the needed flexibilities for the implementation and success of MSSP ACOs and the sustainability and encouragement of participation of physical therapists in private practice, home health agencies, skilled nursing facilities, rehabilitation agencies and other non-physician providers.

Safeguards against the Proliferation of Physician Owned Physical Therapy Services

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 Patient Protection and Affordable Care Act of 2010 (ACA) is that the MSSP program redesign care processes in a manner that promotes high quality and efficient service delivery. Therefore, we strongly believe that to the extent possible, the waiver of the Stark, anti-kickback and CMP laws, should seek to impede physician ownership of designated health services such as physical therapy.

The main provision 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. Of particular concern to the profession of physical therapy are the increasing instances of physician-owned physical therapy service models appearing across the country.

Physician ownership of physical therapy services 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 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 purpose of this exception was 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 entities they own 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. By eliminating physical therapy as a DHS furnished under the IOAS exception, we believe CMS and OIG would reduce a significant amount of programmatic abuse, prevent overutilization of services and enhance the quality of patient care. Therefore, we continue to urge CMS and OIG to restrict the ownership of physician-owned physical therapy services in ACOs formed under the MSSP.
In the interim final rule, CMS and OIG expressly state that in order for the ACO to qualify for protection under one of the waivers, the arrangement must be “reasonably related to the purposes of the MSSP”. APTA strongly contends that physician ownership of physical therapy services does not meet this stated thrust, and therefore should not be allowed under the promulgated waivers.

We believe that this is true for the following reasons. First, there are other practice settings, such as independent physical therapists in private practice, hospitals, and rehabilitation agencies, that could deliver physical therapy services to beneficiaries assigned to the ACO. Second, the quality reporting system set forth by CMS in the MSSP final rule does not contain the adequate measures to ensure that arrangements in which physicians own physical therapy services truly result in improved quality of care to the Medicare beneficiary.

Therefore, we assert that it is wholly inappropriate to allow physician ownership of physical therapy services under the MSSP waivers and that ACOS formed under the MSSP can provide medically necessary physical therapy services through arrangements with independent physical therapy clinics, rehabilitation agencies and other physical therapy providers.

Clarification of Interaction between Current Stark II IOAS Exception and Interim Final Waivers

As aforementioned, APTA is strongly opposed to the current loopholes created by the IOAS exception. Therefore, we are very concerned of any expansion or further relaxation of this exception that may result from the implementation of these fraud and abuse waivers. We interpret this interim final rule to mean that the waivers do not alter the requirements necessary to fit within the IOAS exception. Rather, it is our interpretation that physician ownership of physical therapy services can continue to exist under the current exception, but compliance with the requirements under the current IOAS exception law remains necessary.

In fact, a waiver from the physician self-referral law would not be applicable for these models according to the language from the interim final rule that states “a waiver of a specific fraud and abuse law is not needed for an arrangement to the extent that the arrangement…implicates the law, but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law.” To make this point more clear, we strongly urge CMS and OIG to confirm this interpretation in its response to comments regarding the interim final rule.

Implication for Abusive and Fraudulent Behavior Posed by the Implementation of the “Compliance with the Physician Self-Referral Law” Waiver

Although we believe this interim final rule does not substantively change the existing requirements needed to fit within the IOAS exception, APTA is greatly concerned about the broad application of the “compliance with the physician self-referral law” waiver. Under this waiver, the gainsharing CMP and federal anti-kickback laws are waived for any financial relationship between or among the ACO, its participants and its ACO providers/suppliers provided that: (1) the ACO has entered into a participation agreement and remains in good standing under its participation agreement; (2) the financial relationship is reasonably related to the purposes of the MSSP; and (3) the financial relationship fully complies with an exception under the Stark physician self-referral law.

According to the interim final rule, this waiver was created so that entities using an existing Stark physician self-referral exception need not undertake a separate legal review under the federal
anti-kickback statute or gainsharing CMP. APTA believes that the convenience achieved through the lack of separate legal review comes at too high a risk that models fitting within an exception will enter into abusive relationships to the detriment of Medicare beneficiaries and the Medicare program.

Even though APTA disagrees with the inclusion of physical therapy services as a DHS permissible service under the IOAS exception, we appreciate the balance that the anti-kickback statute protection offers within physician owned physical therapy models. If the anti-kickback statute protection is eliminated, the potential for abusive behavior will be twofold.

First, physicians will not only be able to own physical therapy services, but they will also be permitted to give financial incentives to providers to create physician-owned physical therapy services models. Second, automatically waiving the anti-kickback protection will allow physicians to give financial incentives to patients to receive their services within physician-owned physical therapy services models. This freedom to incentivize both providers and patients under the physician owned physical therapy practice model induces abusive and fraudulent practices that may lead to overutilization and lower quality of care to the patient.

Therefore, APTA strongly urges CMS and OIG to eliminate the “compliance with the physician self-referral law” waiver from the interim final rule. Should an arrangement seek waiver of the federal anti-kickback statute and the gainsharing CMP laws, we believe these arrangements should be scrutinized through the requirements under the ACO participation waiver.

In the alternative, at the very least, we ask that financial relationships qualifying for the “compliance with the physician self-referral law” waiver be subject to audit and oversight functions throughout their existence.

Lastly, CMS and OIG state that the waiver applies until the participation agreement ends, including renewals, expirations or terminations, but that the Agencies are considering providing an additional 3 to 12 months continuation period. We believe that an extension of the applicability of this waiver for any period beyond the expiration of the ACO participation agreement is wholly inappropriate and therefore should not be allowed.

**Safeguards against Abusive Beneficiary Inducements**

Another aspect of this interim final rule that greatly concerns APTA is the expansive flexibilities afforded to MSSP ACOs to establish beneficiary inducements. The “Waiver for Patient Incentives” defers significant provisions of the CMP and federal anti-kickback laws for items or services provided by an ACO, its ACO participants, or its ACO providers/suppliers to beneficiaries for free or below fair market-value if all four of the following conditions are met: (1) The ACO has entered into a participation agreement and remains in good standing under its participation agreement; (2) There is a reasonable connection between the items or services and the medical care of the beneficiary; (3) The items or services are in-kind; and (4) The items or services are for preventative care; adherence to a treatment regime, drug regime, or follow-up care plan; or management of a chronic disease.

We strongly oppose the implementation of this waiver in its current form, as we believe its application is too broad in nature. The prohibitions established under the CMP and federal anti-kickback laws against offering patients remuneration to encourage the use of a particular provider or to induce referrals were rightly promulgated to safeguard against such behavior. It is our fear
that the general applicability of this waiver will create a favorable environment for the fraudulent and abusive behaviors that the OIG has worked diligently to mitigate.

In its current form, a “reasonable connection between items and services and medical care” is open to creative interpretation that can include a wide array of arrangements. Second, “adherence to a treatment regime, drug regime, follow-up care plan or management of a chronic disease” can also be manipulated to fit most items and services furnished by the ACO. Therefore, we recommend that CMS and OIG review this waiver and narrow its application and scope by more specifically defining “reasonable connection” in the context of quality measurement and outcomes and by limiting its applicability to items and services for preventative care only.

Furthermore, CMS and OIG seek comment on whether this waiver should be limited to beneficiaries assigned to the ACO. As articulated, we are opposed to the application of this waiver in its current form for all beneficiaries, but at a minimum, we strongly urge CMS to limit this waiver to only beneficiaries assigned to the ACO. We believe that the ability to apply this waiver to non-ACO patients presents an unfair advantage to ACOs over other Medicare providers outside of the ACO as well as an unnecessary avenue for fraudulent behavior.

Application of Waivers to Non-ACO Business

In the interim final rule, CMS and OIG have requested comments on whether the waivers should apply to non-ACO business. In the interest of prohibiting against unfair competition, APTA strongly contends that the waivers should not apply to the furnishing of items or services by an ACO participant, professional or provider/supplier outside of their ACO participation agreement with CMS and/or contractual agreement to participate in the ACO as there is no benefit to the Medicare program or the beneficiary.

The application of these waivers beyond ACO business poses a tremendous risk to anti-trust laws and patient freedom of choice and undermines the stated intent of the waivers as such activities are not “reasonably related to the purposes of the MSSP”.

Waiver Implications for Existing State Laws

Lastly, APTA is concerned about the intersection between these waivers and existing state laws that protect against health care fraud and abuse. While we understand that these waivers do not provide any express preemption of the state laws, we are very concerned that there are several state laws that may prevent providers such as physical therapists from participating in ACO arrangements with hospitals, physicians and other health care providers.

As stated earlier, we believe that physical therapists will become integral to the success of ACOs and other integrated models of care. Accordingly, we want to ensure that there are no impediments to the physical therapist becoming meaningful participants in the MSSP. Therefore, we urge CMS and OIG to review the following list of state laws that we believe may prohibit physical therapists from participating in the MSSP and work with the states to craft specific carve outs for participation in the MSSP while retaining the fundamental prohibitions against physician ownership of physical therapy services as established under these state laws.

Arizona: §32-2044. Grounds for disciplinary action. The following are grounds for disciplinary action:
11. Directly or indirectly requesting, receiving or participating in the dividing, 
transferring, assigning, rebating or refunding of an unearned fee or profiting by 
means of any credit or other valuable consideration such as an unearned 
commission, discount or gratuity in connection with the furnishing of physical 
therapy services. This paragraph does not prohibit the members of any regularly 
and properly organized business entity recognized by law and comprised of 
physical therapists from dividing fees received for professional services among 
themselves as they determine necessary to defray their joint operating expense.

Arkansas: §17-93-308. Revocation, suspension, or denial - Grounds. 
(9)(A) Engages, directly or indirectly, in the division, transferring, assigning, 
rebating, or refunding of fees received for professional services or gratuity with 
any physician or health care practitioner who referred a patient, or with any 
relative or business associate of the referring person, without appropriate 
disclosure to the patient so referred.

Delaware: §2616. Grounds for refusal, suspension or revocation of license or 
registration; penalties for violations of chapter. 
(8) Engages directly or indirectly in the division, transferring, assigning, 
rebating or refunding of fees received for professional services or who profits by 
means of a credit or other valuable consideration such as wages, an unearned 
commission, discount or gratuity with any person who referred a patient, or with 
any relative or business associate of the referring person. Nothing in this 
paragraph shall be construed as prohibiting the members of any regularly and 
properly organized business entity recognized by Delaware law and comprised of 
physical therapists or athletic trainers from making any division of their total 
fees among themselves as they determine by contract necessary to defray their 
joint operating costs. This paragraph shall not apply to physical therapist or 
athletic trainer positions currently held by physical therapists or athletic trainers 
employed by licensed medical and osteopathic physicians.

Florida: §486.125 Refusal, revocation, or suspension of license; administrative fines and 
other disciplinary measures. 
(f) Engaging directly or indirectly in the dividing, transferring, assigning, 
rebating, or refunding of fees received for professional services, or having been 
found to profit by means of a credit or other valuable consideration, such as an 
unearned commission, discount, or gratuity, with any person referring a patient 
or with any relative or business associate of the referring person. Nothing in this 
chapter shall be construed to prohibit the members of any regularly and properly 
organized business entity which is comprised of physical therapists and which is 
recognized under the laws of this state from making any division of their total 
fees among themselves as they determine necessary.

Idaho: §54-2218. Grounds for Disciplinary Action 
(11) Directly or indirectly requesting, receiving or participating in the dividing, 
transferring or assigning, of any referral fee from any health care professional 
licensed or regulated by the state of Idaho, or any other third party, or profiting 
by means of a credit or other valuable consideration such as an unearned 
commission, discount or gratuity in connection with the furnishing of physical 
therapy services. Nothing in this paragraph prohibits the members, owners, 
shareholders or partners of any regularly and properly organized business entity
recognized by the laws of the state of Idaho and comprised of physical therapists from dividing fees received for professional services amongst themselves.

**Louisiana: §2413. Refusal, suspension, or revocation of license.**

(8) Engages directly or indirectly in the division, transferring, assigning, rebating, or refunding of fees received for professional service with a referring practitioner or any relative or business associate of that referring practitioner. Nothing in the this paragraph shall be construed as prohibiting the members of any regularly and properly organized business entity recognized by law and comprised of physical therapist from dividing that amount of fees received for professional service among themselves as they determine by contract necessary to defray their joint operating expense.

**Missouri: §334.253. 1. Physicians prohibited referral to certain physical therapists, when, financial relationship, defined--exceptions, effective when.**

A physician may not make a referral to an entity for the furnishing of any physical therapy services with whom the physician, physician's employer, or immediate family member of such referring physician has a financial relationship. A financial relationship exists if the referring physician, the referring physician's employer, or immediate family member:

(1) Has a direct or indirect ownership or investment interest in the entity whether through equity, debt, or other means; or

(2) Receives remuneration from a compensation arrangement from the entity for the referral.

**New Jersey: §11 of P.L.1983, c.296 No physical therapist or physical therapist assistant shall engage directly or indirectly in the division, transferring, assigning, rebating or refunding of fees received for professional services or pay or accept fees or commissions for referrals for professional services; however, nothing in this section shall be construed to prohibit physical therapists who are members of a professional association or other business entity, properly organized pursuant to law, from making a division of fees among themselves as determined by contract to be necessary to defray joint operating costs or pay salaries, benefits, or other compensation to employees.

**South Carolina: §40-45-110. Refusal to grant licenses; suspensions, revocations, or other restrictions; grounds; mental and physical exams allowed; evidentiary use of records; opportunity to demonstrate ability to practice.**

(1) requests, receives, participates, or engages directly or indirectly in the dividing, transferring, assigning, rebating, or refunding of fees received for professional services or profits by means of a credit or other valuable consideration including, but not limited to, wages, an unearned commission, discount, or gratuity with a person who referred a patient, or with a relative or business associate of the referring person.

**Tennessee: §23. The committee has the power, and it shall be its duty, to deny, suspend, revoke the license of, or to otherwise lawfully discipline, a licensee who is guilty of violating any of the provisions of this part or is guilty of the following acts or offenses:**

(11) Directly or indirectly requesting, receiving, or participating in the dividing, transferring, assigning, rebating or refunding of an unearned fee, or profiting by means of a credit or other valuable consideration such as an unearned commission, discount, or gratuity in connection with the furnishing of physical
therapy services. Nothing in this item prohibits the members of any regularly and properly organized business entity recognized by law and comprised of physical therapists from dividing fees received for professional services among themselves as they determine necessary to defray their joint operating expense.

**Wyoming:** §33-25-111. *Denial, suspension or revocation of license or registration.*

(x) Engages directly or indirectly in the division, transferring, assigning, rebating, or refunding of fees received for professional services or profits by means of a credit or other valuable consideration as an unearned commission, discount or gratuity with any person who has referred a patient, or with any relative or business associate of the referring person. Nothing in this paragraph shall be construed as prohibiting the members of any regularly and properly organized business entity comprised of or including physical therapists from making any division of their total fees among themselves as they determine by contract necessary.

**Conclusion**

In closing, APTA thanks CMS and OIG for the opportunity 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 U.S. 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,

R. Scott Ward, PT, PhD
President

RSW: rdd