June 6, 2011

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

Submitted electronically

RE: File Code CMS-1345-P Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations

Dear Dr. Berwick:

On behalf of the over 78,000 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 Medicare Shared Savings Program: Accountable Care Organizations (ACO) proposed rule published in the Federal Register on April 7, 2011. First, APTA would like to applaud the Centers for Medicare & Medicaid Services (CMS) for taking the first important step toward building an integrated care delivery system that is interdisciplinary, patient-centered, and seeks to improve the quality of care for Medicare beneficiaries throughout the health care continuum, and we look forward to working with the Agency to revise the proposed rule so that it meets its intended purpose.

APTA commends CMS for its work with the Department of Health and Human Services (HHS) Office of the Inspector General (OIG), the Federal Trade Commission (FTC), the Department of Justice (DOJ) and the Internal Revenue Service (IRS) for the massive coordination of their respective Agencies and regulatory authorities in the promulgation of the ACO proposed rules, notices, and statements. We understand the tremendous efforts that were taken to issue a rulemaking of this magnitude and believe that the Agencies should be congratulated for all of their hard work.

APTA is pleased that physical therapists will have the opportunity to participate in ACOs and will continue to actively encourage its membership to improve health care to their patients through innovative health care delivery models including ACOs established under the Affordable Care Act (ACA). As stated in the proposed rule, the
goal of the ACO is to carry out the three-part aim of health care reform, which is to provide better care to individuals, better health for populations, and to lower growth in expenditures. These are goals that the APTA is very committed to achieving as evidenced by our current and past partnerships with CMS in such initiatives as the Physician Quality Reporting System (PQRS), Value Based Purchasing Programs Post-Acute Care Demonstration, and our work with the National Quality Forum (NQF), physician consortium and Ambulatory Quality Alliance (AQA).

The mission of APTA is to further the profession’s role in the prevention, diagnosis, and treatment of movement dysfunctions and the enhancement of the physical health and functional abilities of members of the public. Physical therapists practice in a wide variety of inpatient and outpatient settings, including hospitals, skilled nursing facilities, home health agencies, rehabilitation agencies, physical therapists’ private practice offices, and physician offices in which health care is delivered to Medicare beneficiaries.

APTA strongly urges CMS to recognize the vital role that physical therapists will play in assuring that ACOs provide access to and deliver quality care to Medicare beneficiaries. Although we feel CMS has made positive progress with the ACO model through this proposed rulemaking, we believe that there are several aspects that require significant modifications to create a seamless, integrated model of care that is in the best interest of Medicare beneficiaries.

APTA believes that the proposed rule lacks the appropriate safeguards and operational details that are needed to create a comprehensive program that is quality driven, inclusive of all medically necessary services, substantially mitigates abusive and fraudulent behavior, and is transparent in its legal and organizational structure.

While APTA has provided detailed comments below and under separate cover to the complementary notices released by the FTC, DOJ, and OIG, there are 10 essential revisions that we feel must be made to the proposed Medicare Shared Savings Program (MSSP) before the program can be finalized and implemented into the existing Medicare program. They are as follows:

- CMS should clarify in the final rule that the expanded list of providers that may participate in the MSSP includes physical therapists in private practice, rehabilitation agencies, home health agencies, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, inpatient rehabilitation facilities, and other providers/suppliers not specifically mentioned in the delineated list of ACO professionals.

- CMS should require ACOs make available to all ACO participants financial and legal records in a timely manner before contractual agreements are finalized and throughout the duration of the three-year period. In addition, ACOs should be required to provide clear and concise instructions to ACO participants on compliance and quality reporting requirements, including
timely notification of when and how the ACO has determined that the ACO participant is in non-compliance with the stated terms of their agreement and/or the requirements of the MSSP.

- CMS should revise its interpretation of “meaningful commitment to the ACOs clinical integration.” Financial and human capital is not sufficient to show clinical integration. Real clinical integration is evidenced in patient coordination of care across health care settings, providers, and suppliers.

- CMS should revise the proposed quality measures to ensure that rehabilitation services such as physical therapy are integral components of ACOs. Specifically, CMS should add a sixth domain designated as patient function (activity and participation).

- CMS should recognize the integral role that non-physician providers, such as physical therapists, will play in the successful use of health information technology (HIT), and provide the appropriate financial resources and support that will enable ACO participants such as physical therapists to adopt EHRs.

- CMS should make several clarifications regarding program integrity requirements. Specifically, how audits will be conducted for ACOs and its participants.

- CMS should establish a prohibition against any behavior that seeks to impede referrals or care by professionals who are not participating in the ACO.

- CMS should coordinate with the FTC and DOJ to thwart anti-competitive behavior in the formation of ACOs. Specifically, the exclusion of non-physician independent providers by physician groups and hospitals who are considered a threat such as physical therapists.

- CMS and the OIG should closely monitor ACOs to ensure that exceptions to the self-referral (Stark II) laws, such as the in-office ancillary services exception, do not result in abusive arrangements and referral practices on the part of the ACO.

- CMS and the OIG should expressly prohibit ACOs from waiving co-pays, giving deep discounts, or offering other incentives to ACO patients in order to incentivize them to receive services within the ACO.
The American Physical Therapy Association’s Comments to the Medicare Shared Savings Program Proposed Rule

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Eligible Entities

The Social Security Act [herein referred to as the Act] §1899(b) establishes eligibility requirements for ACOs participating in the Medicare Shared Savings Program (MSSP). Section 1899(b)(1) of the Act allows several designated groups of providers of services and suppliers to participate as an ACO as determined appropriate by the Secretary [of HHS] and under the condition these providers and suppliers have established a mechanism for shared governance. The ACA lists the following groups of providers of services and suppliers as eligible to participate as an ACO:

- ACO professionals in group practice arrangements.
- Networks of individual practices of ACO professionals.
- Partnerships or joint venture arrangements between hospitals and ACO professionals.
- Hospitals employing ACO professionals.
- Such other groups of providers of services and suppliers as the Secretary determines appropriate.

Section 1899(h)(1) of the Act defines “ACO professional” as a physician defined in §1861(r)(1) which includes doctors of medicine or osteopathy, or a practitioner as defined in §1842(b)(18)(C)(i) which includes physicians assistants, nurse practitioners, and clinical nurse specialists.

In the proposed rule, CMS exercises its statutory authority to add certain critical access hospitals to this list. CMS also proposes that ACOs may incorporate other groups of Medicare-enrolled providers and suppliers, many of whom would not be able to form ACOs and participate in the program independently. Each Medicare-enrolled provider and supplier that joins together to form an ACO is identified by their Medicare-enrolled taxpayer identification number (TIN). These individuals are referred to in the proposed rule as “ACO participants”.

CMS goes on to state that,

“...the benefits of limiting eligibility need to be balanced against the prospect that such limitations could compromise potential innovations and forfeit the opportunity to assess new models that could potentially transform health care in ways that improve quality and beneficiary satisfaction while better controlling costs. More importantly, defining eligibility narrowly also has the potential to impede development of ACOs that include other provider and supplier types, especially those that provide services in rural and other underserved areas.”

APTA wholeheartedly agrees with this statement and commends the Agency for defining the terms “ACO participant” and “ACO provider/supplier” in a way that allows broad
participation in ACOs by Medicare-enrolled providers and suppliers, including physical therapists, and also allows them to share in any savings an ACO might produce. We strongly believe that the success of the ACO model in improving the quality of care and decreasing costs will depend on the collective efforts of all health care providers throughout the health care spectrum, including physical therapists, home health agencies, rehabilitation agencies, inpatient rehabilitation facilities, skilled nursing facilities and other provider types. Therefore, we strongly recommend that CMS clarify in the final rule that the expanded list of eligible groups of providers that may participate in the MSSP includes physical therapists and the other aforementioned groups.

Sufficient Number of Providers and Beneficiaries

Section 1899(b)(2)(D) of the Act requires participating ACOs to include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO and at a minimum that the ACO must have at least 5000 Medicare beneficiaries assigned to it. Therefore, CMS proposes that an ACO would be determined to have a sufficient number of primary care ACO professionals to serve the number of Medicare beneficiaries assigned to it if the number of beneficiaries historically assigned over the three-year benchmark period using ACO participant tax-identification numbers (TINs) exceeds the 5000 threshold each year.

While we recognize that it is important to ensure that there are a sufficient number of primary care providers within an ACO to treat Medicare beneficiaries, primary care providers, alone, will not determine the success or failure of the ACO. To ensure that patients are receiving the high quality and cost-saving services mandated under the Act, ACOs will need to provide the full spectrum of comprehensive services that its patient population requires for the appropriate treatment of their injury, illness or condition. This includes services provided by physical therapists and other non-physician providers.

Therefore, APTA strongly urges CMS to set requirements that all sufficient health care items and services are available to meet the needs of the ACO patient population. Section 3022 of the ACA establishes a program that promotes accountability for a patient population, coordinates items and services under Medicare Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery, and we believe that requiring ACOs to illustrate that they have requisite services to treat their assigned Medicare beneficiaries is an important element of this mandate. ACOs should demonstrate that essential services such as physical therapy are provided within the ACO or the ACO has the appropriate referral relationships in place so that patients have access to these services. We recommend that CMS require ACOs to include this information on their application prior to approval of the entity as a MSSP ACO. In addition, CMS should also capture this information through patient surveys when inquiring about patient access to care similar to the current
methods employed in the Consumer Assessment of Healthcare Providers and Systems (CAHPS) program.

**Legal and Governance Structure**

As mandated by §1899(b)(1)(A) of the Act, the proposed rule delineates that ACOs are required to have a formal and legal structure that would allow the organization to receive and distribute payments for “shared savings to participating providers of services and suppliers” and ACO participants to have a “mechanism for shared governance” in order to participate in the program. Therefore, ACOs must have a legal structure that provides both the basis for its shared governance as well as the mechanism for it to receive and distribute shared savings payments to ACO participants and ACO providers/suppliers. The ACO legal entity may be structured as a corporation, partnership, LLC, foundation, or any other entity permitted by State law.

Throughout the health care debate, the Administration and the Congress have asked for more transparency within the health care system. Transparency is essential to controlling volume of services delivered, preventing price-fixing and ensuring quality. The tangible actions of transparency include requiring providers to publicly report clinical data, insurers to publish information regarding pricing, and providers to furnish information to patients regarding their business structure and affiliations. Such information fosters better evidence-based practices and quality benchmarks from health care providers, allows public and private payers to make more informed decisions when purchasing care, and empowers patients to choose the best quality health care that meets their specific needs.

The MSSP proposed rule seeks to create an ACO model that reaches the aim of transparency in many respects, but APTA believes the Agency can make improvements to the proposed model. Due to the unique delivery model that is created by the ACO, the issue of transparency is not only important for purposes of informing the Medicare beneficiary so that they can make prudent decisions about purchasing and choosing health care options, but transparency is equally important for health care providers such as physical therapists so that they can make educated decisions on whether to enter into agreements with ACOs.

Therefore, APTA strongly urges CMS to require that ACOs, in good faith, make available to all ACO participants financial and legal records in a timely manner before contractual agreements are finalized and throughout the duration of the three-year period. In addition, ACOs should be required to provide clear and concise instructions to ACO participants on compliance and quality reporting requirements, including timely notification of when and how the ACO has determined that the ACO participant is in non-compliance with the stated terms of their agreement and/or the requirements of the MSSP. This level of transparency is needed to ensure that ACO participants are not susceptible to unfair business practices.
and are treated on a level playing field with the ACO professionals, such as physicians and hospitals.

**Leadership and Management**

Section 1899(b)(2)(F) of the Act requires that an ACO have in place a leadership and management structure that includes clinical and administrative systems. Based on the work conducted in the Medicare Physician Group Practice (PGP) Demonstration, CMS identifies several factors that are critical to improving quality and the opportunity for shared savings. These include:

- An integrated organization with an environment that supports expending resources on multiple programs and initiatives to improve quality and reduce unnecessary services.
- Dedicated physician leadership with a proven ability to motivate development and implementation of quality improvement and other clinical programs and initiatives.
- Health information technology that facilitates the aggregation and analysis of data, allows patient-level feedback, and provides alerts and reminders at the point of care.
- Experience with non-Medicare payer initiatives, particularly through a managed care affiliate, to improve quality and reduce expenditure growth.

To achieve these factors, CMS proposes that ACO operations be managed by an executive, officer, manager, or general partner whose appointment and removal is under the control of the organization’s governing body and whose leadership team demonstrates the ability to influence or direct clinical practice to improve efficiency processes and outcomes. Clinical management and oversight would be managed by a senior-level medical director who is a board-certified physician, licensed in the State in which the ACO operates, and physically present in that State.

The proposed rule also indicates that ACO participants and ACO providers/suppliers would have a meaningful commitment to the ACO’s clinical integration program to ensure success. This may include a meaningful financial investment in the ACO, meaningful human investment in the ongoing operations of the ACO such that potential loss or recoupment of the investment is likely to motivate the participant to make the clinical integration program succeed. ACOs would have a physician-directed quality assurance and process improvement committee that would oversee an ongoing quality assurance and improvement program that would be accountable for meeting performance and compliance standards.

**APTA strongly urges CMS to revise its interpretation of “meaningful commitment to the ACO’s clinical integration.” We contend that financial and human capital is**
not sufficient to show clinical integration. Real clinical integration is evidenced in patient coordination of care across health care settings, providers, and suppliers. Clinical integration is best shown when there is a structure in place that is patient-focused and where clinicians collaborate on best practices in an effort to furnish higher quality care that they likely would not achieve if working independently. These are elements highlighted in the proposed rule when discussing quality reporting measures and implementing evidence-based patient processes and thus, these are the aspects of this rule that CMS should focus on when assessing clinical integration.

APTA is deeply concerned that CMS or ACOs will have expectations with respect to the level of “meaningful commitment” that ACO participants such as physical therapists, particularly those in solo or small practices, would be unable to reach in a reasonable and practical manner. While these smaller practices have much to add to ACOs in the area of quality care and improved outcomes, they have limited financial resources and staff and cannot sustain large divestures of their assets and staff. In the final rule, CMS should set clear terms regarding what is meant by “meaningful financial and human investment”. These terms should be defined in a manner that does not place undue administrative or financial burden on ACO participants and ACO providers/suppliers and there should be measures that safeguard against insolvency of these practices due to their participation in an ACO.

Likewise, the start up costs for ACO implementation will be significant for ACO professionals. It is estimated that start-up costs can range from $11.6 million to $26.1 million to launch an ACO and manage it for the first year and it may take some time for the ACOs to see a return of investment. While we appreciate efforts to mitigate the burden of start-up costs such as the Advanced Payment Initiative announced by the Centers for Medicare and Medicaid Innovation (CMMI), smaller ACO participants, such as physical therapists in private practice, are not prepared to assume such a financial burden and it is our fear that ACOs will look to their ACO participants and ACO providers/suppliers to bear some of the start-up costs in order to be a part of the ACO. Therefore, we strongly encourage the Agency to provide grants and other funding sources to alleviate the burden of ACO start-up costs to physical therapists and other ACO participants and ACO providers/suppliers.

CMS states that it envisions that an ACO governance structure should allow for appropriate proportionate control for ACO participants, giving each ACO participant a voice in the decision making process and be sufficient to meet the statutory requirements regarding clinical and administrative systems. Furthermore, the governing body of the ACO should be comprised of the ACO participants or their designated representatives, include at least one Medicare beneficiary served by the ACO, and possess broad

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1 American Hospital Association. Trend Watch: Clinical Integration – The Key to Real Reform (February 2010).

responsibility for the ACO’s administrative, fiduciary, and clinical operations. Each ACO participant must choose an appropriate representative from within its organization to represent them on the governing body.

APTA commends CMS for the inclusion of this proposal as we also believe that all ACO participants should be represented within the ACO governing board. We believe that this proposal will also aid CMS, FTC, and DOJ in their efforts to thwart anti-competitive behavior among ACO models. To strengthen this proposed requirement, APTA recommends that CMS establish a mechanism for ACO participants to share information and/or voice concerns regarding unfair business practices or non-compliance with MSSP requirements directly to the Agency. In addition, CMS should establish a process for ACO participants to challenge the ACO once a determination of termination of the ACO participant from the ACO has been made.

CMS acknowledges that comments were received about the participation of private entities other than ACO participants in ACOs and states that it understands that this may be needed for small entities that do not have the resources to form ACOs. Therefore, CMS proposes that in order to be eligible for participation in the MSSP, the ACO participants must have at least 75 percent control of the ACO’s governing body. APTA understands CMS’ rationale for allowing the inclusion of these private entities in the ACO and supports the adoption of this proposal along with the requirement that the ACO participants retain the controlling portion of the ACO. However, we urge CMS to monitor this aspect of the ACO structure very closely. In the spirit of transparency as we discussed earlier, we recommend that CMS require detailed explanations of how the private entities are contracted with the ACO and any information regarding how these private entities are reimbursed for services rendered to Medicare beneficiaries.

Distribution of Shared Savings and Losses

Another element of the proposed rule that greatly concerns APTA is the distribution of shared savings among the ACO participants and ACO providers/suppliers. We strongly believe this aspect of the rule has the potential to create abusive and unfair practices if not structured properly. CMS proposes to make any shared savings payments directly to the ACO as identified by its TIN and to require ACOs to provide a description in their application of the criteria they plan to employ for distributing shared savings among ACO participants and ACO providers/suppliers, and how any shared savings will be used to align to the three-part aim. In the proposed rule, CMS specifically states:

“While section 1899(b)(2)(C) of the Act requires an ACO to have a formal legal structure that would allow the organization to receive and distribute payments for shared savings to participating providers of services and suppliers, the statute does not establish any requirements for the manner
in which shared savings payments are distributed. We have considered whether it would be appropriate, under the broad discretion granted to the Secretary in implementing the Shared Savings Program, to propose criteria for the distribution of shared savings by the ACO. Although we do not believe we have the authority to specify how shared savings must be distributed (so long as the distribution is consistent with all applicable legal requirements), we believe it would be consistent with the purpose and intent of the statute to require the ACO to indicate as part of its application how it plans to use potential shared savings to meet the goals of the program. More specifically, ACOs would have to indicate how potential shared savings would be used to promote accountability for their Medicare population and the coordination of their care as well as how they might be invested in infrastructure and redesigned care processes for high quality and efficient health care service delivery. Therefore, we propose to require ACOs to provide a description in their application of the criteria they plan to employ for distributing shared savings among ACO participants and ACO professionals, and how any shared savings will be used to align with the aims of better care for individuals, better health for populations, and lower growth in expenditures. We believe the proposed requirement would achieve the most appropriate balance among objectives for encouraging participation, innovation, and achievement of program while still focusing on the aims of better care for individuals, better health for populations, and lower growth in expenditures. Additionally, it is the intention of this requirement for ACOs to include this description in the application, to both guard against improper financial incentives as well as ensure appropriate beneficiary protections.”

While we agree with this statement, we strongly recommend that CMS exercise its statutory authority and require that ACOs not only provide a description in their application of how they plan to distribute shared savings among ACO participants and providers/suppliers and how these distributions will align with the three part aim, but CMS should also require that the ACO in its application demonstrate that savings will be distributed in a fair and equitable manner to large and small ACO participants and ACO providers/suppliers. We believe this information should be closely monitored to guard against unfair business practices and to promote a fair and equitable distribution of shared savings for all participants and professionals who are a part of the ACO. CMS should also mandate that ACOs distribute shared savings to ACO participants and providers/suppliers in a timely manner.

In the proposed rule, CMS proposes a flat 25 percent withholding rate be applied annually to an ACO’s earned performance payment. This withholding would serve as a component of the repayment mechanism that ACOs will need to establish to ensure their ability to repay Medicare for incurred losses. CMS also sets forth options for additional
payment mechanisms that the ACO must choose from to ensure that it can repay Medicare for any losses incurred. In addition, CMS proposes to implement both a one-sided risk model (sharing savings only for the first two years and sharing of savings and losses in the third year) and a two-sided risk model (sharing of savings and losses for all three years) and allow the ACO to choose which risk model will govern its operations.

The proposed rule explicitly states that one option for an ACO, with respect to a self-executing mechanism for repaying shared losses, would be an ACO’s indication that funds may be recouped from Medicare payments to the ACO’s participants. We strongly disagree with this proposed option for repayment of losses as we believe that this will severely impede some providers/suppliers from participating in the ACO.

Therefore, APTA strongly urges CMS to state in the final rule that the repayment of losses will be made directly from the ACO and CMS will not seek to withhold payments from Medicare claims submitted to the Agency from ACO participants, providers and suppliers who are a part of the owing ACO. Additionally, we recommend that CMS indicate in its legal and governance requirements that all ACO participants and ACO providers/suppliers should have a voice in the decision as to which risk model is chosen (one-sided risk versus two-sided risk model).

**Quality and Reporting Requirements**

CMS proposes to define quality performance standards at the reporting level for the first year of the Shared Savings Program and to define it based on measure scores in subsequent program years. CMS proposes 65 measures for use in the calculation of the ACO Quality Performance Standard.

CMS has identified 5 key domains within the dimensions of improved care and improved health to serve as the basis for assessing, benchmarking, rewarding, and improving ACO quality performance. They are:

- Patient/Caregiver Experience
- Care Coordination
- Patient Safety
- Preventive Health and
- At-Risk Population/Frail Elderly Health

While we completely agree that reporting of quality measures is a critical component to ensuring the success of the MSSP, APTA strongly urges CMS to ensure that there is a robust set of quality measures that apply to ACOs to reduce any financial incentives to decrease utilization and to ensure that ACOs are meeting the goals of the program. In addition to the measures proposed in the rule, we strongly recommend that CMS revise the proposed quality measures to ensure that rehabilitation services such as physical therapy are integral components of ACOs. If strong
quality measures are not in place, there is the potential for lack of beneficiary protection against underservice.

Specifically, APTA first recommends that CMS add a sixth domain designated as patient function (activity and participation). The patient’s ability to function and participate in society is critical to obtaining positive outcomes. A growing percentage of the U.S. population has disabling conditions that limit their ability to carry out the major activities of their age group. As the number of older adults increases, their vulnerability to injury and limitations of their activities of daily living increases as well. This increase in vulnerability and decreased function results in an escalation of the utilization of health care resources. A focus on ensuring that individuals remain independent and functioning members of society throughout their lives will lessen the burden of disability on health care resources. For example, a physician may prescribe medication to a patient with a cardiac disease to manage his/her cholesterol and blood pressure, but if the patient is not active or participating in his/her regular activities of daily living (ADLs), he/she will become more dependent on medication and other costly medical treatments and require more health care resources.

Second, many of the quality measures that have been put forth are specific to physician practice, and in exploring alternative payment models, CMS must take into account the importance of all interdisciplinary team members that make safe, high quality care possible. As an example, the importance of patient satisfaction metrics is one essential part of rating the quality of care from the patient and caregiver’s experience. The ACO proposal does include these metrics as represented by data collected from CAHPS, but CAHPS measures included in this proposal are provider metrics specific to the physician. Given the focus on successful transitions in care, the need to evaluate patient satisfaction with other aspects of care, such as home health, may be equally as important and should be considered for inclusion in the ACO quality metrics where appropriate.

Providing comprehensive, interdisciplinary care requires a team of professionals. The ACO proposal mentions the use of teams, including inter-professional teams, but puts forth a quality structure that is based almost entirely on the performance of physicians. APTA believes that this is not consistent with the concept of patient care across the continuum. The ACO proposal discusses an aggregate quality score across the domains, requiring that ACOs report on all quality measures to be eligible for savings. The rationale for this quality scoring requirement is aimed at holding ACOs “accountable across the continuum of care”; we fail to realize how this is possible when the measures can be fulfilled by the actions of one main discipline (physicians) in limited setting practices as defined by the minimum requirements of an ACO.

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Third, APTA acknowledges that improving transitions in care is an important component in health care reform. Approximately 20 percent of all Medicare patients are readmitted within 30 days of an acute care discharge and readmissions account for an estimated $15 billion in health care spending. Strategies to improve transitions in care have been documented and include a variety of interventions from patient engagement and education, to follow-up calls to more complex multidisciplinary interventions in high-risk populations. There are 4 measures included in the ACO proposal that aim to measure readmissions and transitions in care (measures 8 through 12). We support the inclusion of readmission as an outcome measure for transitions in care, and also believe that the measure of medication reconciliation and the multi-dimensional care transition measure aim to capture important components of the patient’s transition process. We believe, however, that measure 9 (30-day physician follow-up) does not have sufficient evidence to support its conclusion, and in fact, a recent study suggests that 30-day physician follow-up did not impact readmissions.

We support the inclusion of high-risk populations in the proposed measure domains. The significance of caring for diabetic patients, a recognized high-risk population, is an important part of ensuring better care for individuals and populations. APTA is pleased to see the inclusion of measures specific to this patient population, but does have concerns about the exclusion of measures that we feel are vital in ensuring the health of this population. The annual incidence of diabetic foot ulcers has been estimated at 5 percent, with an approximate cost of $7,000 to $10,000 per episode for uncomplicated ulcers, while those ulcers with delayed healing or complications may cost up to 6 times that amount per person. Furthermore, ulcers with complications may lead to amputation with more than 60% of all non-traumatic amputations being related to diabetes. The ACO quality measures do include an annual foot examination measure, however, this only ensures that there is no visible evidence of skin breakdown; it does not assess the risk of foot ulceration for patients who suffer from peripheral neuropathy. The risk of


foot ulceration is better assessed by including a neurologic examination of the lower extremity, a measure endorsed by NQF (0417), in addition to a footwear evaluation which is an additional measure aimed at the prevention of diabetic foot ulcers (NQF 0416).

Another high-risk population identified in the ACO proposal is the frail elderly. As with the inclusion of diabetes and heart failure, APTA is pleased to see specific quality measures identified for this population. Screening for risk of falls is an important component of risk reduction and prediction of falls in the elderly; however, the process of performing the falls screening does not ensure that an appropriate falls plan will be put into place to prevent falls for these patients. **APTA strongly recommends the inclusion of the two-part falls risk assessment and plan of care measures (PQRS 154 and 155) to replace the existing falls measure proposed. This will allow for both the screening and appropriate falls intervention in this high-risk population.**

Fourth, APTA recommends that CMS waive the Medicare financial limitation on outpatient therapy services (i.e. therapy cap) and therapy plan of care physician certification requirements¹⁰ for purposes of the ACO. ACO professionals and participants providing care within the ACO model should understand and be working toward the health care reform three part aim. Therefore, APTA believes that these requirements when in place within this health care delivery model, are unnecessary, could result in the denial of appropriate access to medically necessary services, and cause undue administrative burden that could impact cost.

Last, CMS proposes that each ACO make its quality performance standard scores available to the public. APTA urges CMS to screen this information first with ACOs to ensure data accuracy. Data errors have been known to occur in reporting, and this is especially true with new measures. **The ACO participants and ACO providers/suppliers who are accountable for quality performance should have time to review and dispute any data issues or errors prior to public reporting.**

**Promoting Evidence-Based Medicine**

Section 1899(b)(2)(G) of the Act requires that an ACO define a process to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies.

¹⁰Social Security Act § 1861(r)
42 CFR 424.24 (e)
42 CFR 410.61(e)
First, APTA defines evidence-based practice as access to, and application and integration of evidence to guide clinical decision-making to provide best practice for the patient/client. Evidence-based practice includes the integration of best available research, clinical expertise, and patient/client values and circumstances related to patient/client management, practice management, and health care policy decision-making. Aims of evidence-based practice in the physical therapy context include enhancing patient/client management and reducing unwarranted variation in the provision of physical therapy services.

To promote improved quality of care and patient/client outcomes, APTA supports and promotes the development and utilization of evidence-based practice that includes the integration of best available research, clinical expertise, and patient values and circumstances related to patient/client management, practice management, and health policy decision-making.

APTA has advocated the use of evidence by producing evidence-based clinical practice resources, such as the development of the Hooked on Evidence\textsuperscript{11} database, which allows APTA members to access information from the peer-reviewed literature on the effectiveness of physical therapy interventions. Additionally, through Open Door\textsuperscript{12}, APTA provides its members access to full-text articles from thousands of journals and access to the Cochrane database of systematic reviews.

\textbf{Therefore, APTA recommends that CMS indicate in the final rule that ACO participants and ACO providers/suppliers should seek out professional associations such as the APTA to obtain guidance and resources on how to conduct their practices in a manner that promotes evidence-based practice.}

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\textsuperscript{11} The APTA Hooked on Evidence Website represents a "grassroots" effort to develop a database containing current research evidence on the effectiveness of physical therapy interventions. The Hooked on Evidence project was motivated by a concern that clinicians lacked access to the knowledge available from current research, thus hindering evidence-based practice. The website has the following objectives:

1) Allow members to search a database of article extractions relevant to the field of physical therapy to build support for evidence-based practice  
2) Allow members to contribute extractions of the peer-reviewed literature to the database  
3) List useful web resources and other information consistent with evidence-based practice  
4) Allow members to use clinical scenarios to search the database for relevant article extractions

\textsuperscript{12} Open Door provides APTA members easy access to journals and other resources relevant to clinical practice necessary to carry out evidenced based practices in the physical therapy practices.
**Adopting a Health Information Infrastructure**

Throughout the proposed rule, CMS seeks to implement the §1899(b)(2)(G) of the Act that an ACO:

“...should have a process in place (or clear path to develop such a process) to electronically exchange summary of care information when patients transition to another provider or setting of care, both within and outside the ACO, consistent with meaningful use requirements under the EHR Incentive program. The ACO would be required to describe their process or their plan to develop a process to electronically exchange summary of care information during care transitions.”

While the focus and incentives on the adoption of electronic health records (EHRs) has been placed on hospitals and physicians, APTA strongly believes that the participation of physical therapists in an ACO EHR is vital to the success of the ACO. This will require appropriate resources and support to be furnished under the MSSP for physical therapists to adopt interoperable EHRs that are necessary to communicate and coordinate care with other ACO participants and professionals.

**APTA strongly urges CMS to recognize the integral role that non-physician providers, such as physical therapists, will play in the successful use of health information technology (HIT), and we strongly encourage CMS to provide the appropriate financial resources and support that will enable ACO participants such as physical therapists to adopt EHRs.** Since the ACO model requires a high level of communication amongst providers in order to achieve the goals of the triple aim of health care reform, all providers involved in delivery of services within the ACO should be equally incentivized in order to accomplish a transition to and participation in the use of EHR.

APTA believes EHRs will allow for improved patient and public health outcomes by providing access to real-time health information. For example, an EHR would allow an ACO participant or ACO provider/supplier to determine if a patient has specific drug or other allergies or what medications the patient is taking. In the instance of physical therapy, this information could aid the physical therapist in determining the best method of treatment for the patient or understanding changes in the patient’s condition that will affect their progress toward their defined goals as indicated in the plan of care. Some medications may affect balance and, therefore, limit what a physical therapist can do with that patient. In other instances, knowing that a patient is on cardiac medication(s) would help in clinical decision making to determine which selected interventions to incorporate into a treatment program and document expected physiological response to activity. In addition, it may be possible to conduct disease tracking through HIT that could lead to early interventions to prevent or preclude the worsening of a disease or condition.
The following is an illustration of what a physical therapist would add to an interoperable EHR in an ACO model if given the right resources and support.

**Clinical scenario:** A 70 year old male fell at home and sustained a lumbar fracture with resulting incomplete paralysis to his lower extremities. He is one day status post lumbar decompression with fusion and starting physical therapy.

**Application of EHR:** The inpatient physical therapists at the acute hospital and inpatient rehabilitation hospital are able to use the EHR to access and review the current information regarding his medication, past medical history, previous surgeries, laboratory values, current problem list, post-operative report, demographics, and previous level of function. During the hospital stay the physical therapists continue to use various functions of the EHR to access clinical information, communicate with all of the patient’s other healthcare providers to coordinate care, and document their clinical interventions. Specifically, the physical therapist documents changes in function and develops a problem list using standardized language that is part of the EHR. At the end of the patient’s hospitalization, the patient is transferred home where he starts home health physical therapy. The home health physical therapist is able to access the information that was provided to and by the inpatient physical therapists, including their patient’s level of function when he was discharged. Being part of the ACO and having an interoperable EHR, the home health physical therapist is able communicate directly to the patient’s primary care physician and neurologist. The physical therapist notes that the patient is feeling “unmotivated and depressed” and being less active than when he was at the inpatient rehabilitation facility. The physical therapist documents this and communicates with primary care physician (PCP) directly.

**Coordination of Care:** Arrangements are made for the patient to have a follow-up appointment two weeks earlier than originally scheduled. During the patient’s appointment with his PCP, the physician is able to access the physical therapist documentation and has a better understanding of the patient’s current decline. The PCP adjusts the patient’s medications. Two weeks later, the patient has an improved mood and function. He is able to progress to outpatient physical therapy. Once again, the physical therapist is part of the ACO and able to access the same information that was provided to the inpatient and the home health physical therapist as well as their documentation on the patient’s progress and current problems. In addition, the current medications that the patient is taking have been updated and a current physician problem list is provided. During the outpatient physical therapy evaluation, the physical therapist and the patient agree to focus therapy on improving his mobility impairment of walking long distances, climbing stairs and sleeping through the night so he can participate in his activities related to his busy farm operations, and his family life. To help improve his ability to participate in this activity, the physical therapist focuses part of the interventions on improving control of voluntary movement of the ankle. This goal and the patient’s impairments of muscle tone functions of the patient’s ankle are documented in the EHR. During the patient’s next neurologist appointment, the patient receives a Botox...
injection. The physical therapist is alerted of the neurologist actions through the EHR and assesses the patient to determine if there have been changes in the patient’s condition. Based on their assessment, the physical therapist determines that the patient’s condition has changed and therefore adjustments to the physical therapy interventions are made. After four more weeks and receiving coordinated care between multiple providers, the patient is able to walk long distances on his farm, climb stairs to access the various levels of his environment, and return to spending active time with his family.

As a result of the ACO having an interoperable EHR which all professionals and participants can utilize to record evaluations, treatments and interventions, this patient benefited from optimal coordination of care during transitions of care from inpatient to home health to outpatient which prevented any significant setback in activity. If his abrupt change in mood and function were not managed early, the decreased function could have led to a downward spiral of secondary complications associated with inactivity and potential re-hospitalization. In addition, the increased coordination of care during outpatient physical therapy between the physical therapist and the neurologist led to better and timely communication of the patient’s function which resulted in the patient being discharged from physical therapy in a shorter timeframe while meeting the patient’s goal to enjoy time with his family.

In addition, we recommend that the ACO EHR system must include payment tracking and share allocation distributions components. Adequate tracking mechanisms among ACO participants must be in place to ensure proper distributions, especially due to the complexity of benchmark adjustments and withholdings as discussed in the proposed rule.

Section 1899(b)(2)(G) of the Act also requires:

“...the establishment and use of health information technology, including electronic health records and an electronic health information exchange to enable the provision of a beneficiary’s summary of care record during transitions of care both within and outside of the ACO.”

APTA agrees that EHRs needs to be available both inside and outside of the ACO, since a substantial number of private practice physical therapists and other providers will be administering care but may be outside the ACO. We strongly believe that although operating outside of the ACO, these health care providers will remain an important part of the health care continuum.

**ACO Marketing Guidelines**

In the proposed rule, CMS states the Agency is very concerned about communications that will be sent to the patient and/or provider/supplier regarding their participation in the ACO and the mistaken impression that the ACO is the same as managed care entities.
CMS proposes that all marketing materials, communications, and activities related to the ACO and its participation in the Shared Savings Program (such as mailings and telephone calls) that are used to educate, solicit, notify or contact Medicare beneficiaries and/or providers/suppliers regarding ACO participation be approved by CMS before use and revision. ACOs that fail to meet this requirement may be placed under a corrective action plan or terminated at CMS’ discretion.

APTA strongly supports the CMS proposal for review of the ACO’s marketing materials, and recommends that CMS allow stakeholders to play a major role in developing and/or reviewing the beneficiary educational materials. In addition, we urge CMS to ensure that review is done in an efficient and timely manner so as not to pose an undue burden on the ACO and its participants and providers/suppliers.

CMS also proposes to require providers to post signs in the facilities of participating ACO providers/suppliers indicating their participation in the Shared Savings Program and to make available standardized written information to Medicare FFS beneficiaries whom they serve. ACOs’ written notice would inform beneficiaries of their participation in the Shared Savings Program, the potential for CMS to share identifiable data with ACOs and information on how they can opt-out of having their data shared.

APTA recognizes the importance of ensuring that patients are fully aware of the provider’s participation in an ACO and their rights regarding the sharing of their protected health information, but we request that CMS carefully consider the perception of these postings to patients and any confusion that may be caused to patients who are not a part of the ACO, but who receive services from the provider. For example, the same provider/supplier may participate in more than one ACO, or a Medicare beneficiary being treated by the provider/supplier who is participating in an ACO may not end up being assigned to that ACO. And if retrospective assignment is retained, it is obvious that at the time a patient receives care from a provider/supplier, there will be no way of knowing whether the patient will ultimately be assigned to any ACO that the provider/supplier may be participating in. Further, at this point, it is very difficult to predict how Medicare beneficiaries will react to the ACO concept. All of this will make it challenging for CMS to determine what any signage or other written materials should say about ACOs and a provider/supplier involvement with ACOs.

Program Integrity Requirements

CMS proposes that an ACO have a compliance plan on how it plans to meet the applicable legal requirements. The compliance plan should have the following elements:

- A designated compliance official or individual who is not legal counsel to the ACO and who reports directly to the governing body;
- Mechanisms for identifying and addressing compliance problems related to the ACO’s operations and performance;
• A method for employees or contractors of the ACO to report suspected problems;
• Compliance training of the ACO’s employees and contractors; and
• A requirement to report suspected violations of the law to an appropriate law enforcement agency.

The ACO is ultimately responsible for compliance but CMS also would require that the ACO make the compliance requirements clear in its three-year contract with the ACO participants and ACO providers/suppliers. Therefore, an executive who has the ability to legally bind the ACO must certify the accuracy, completeness and truthfulness of information contained in the Shared Savings Program application, three-year agreement and submissions of quality data and other information. The executive must make a written request to CMS for payment of the shared savings in a document that certifies the ACO’s compliance with program requirements and the accuracy of information sent to ACO professionals and participants.

In the final rule, APTA recommends that CMS delineate that all ACO participants and ACO providers/suppliers compliance plans must be readily available to ACO participants and providers/suppliers when needed.

In the proposed rule, CMS also discusses several measures similar to those used in the Medicare Advantage and Prescription Drug programs that it will employ to ensure program integrity. These measures include:

• Analysis of specific financial and quality data as well as aggregated annual and quarterly reports.
• Site visits.
• Assessment and follow-up investigation of beneficiary and provider complaints.
• Audits (including, for example, analysis of claims, chart review, beneficiary surveys, coding audits).

CMS goes on to state:

“...the Agency anticipates close examination of ACOs that incur large losses to the Medicare program. In order to ensure that we have the information necessary to conduct appropriate monitoring and oversight of ACOs, it will be necessary for ACOs, ACO participants, and ACO providers/suppliers, and other contracted entities performing services and functions on behalf of the ACO to retain records of their activities under the Shared Savings Program for a sufficient period of time to allow the government to conduct the appropriate audits, evaluations, and inspections of their activities.”
In light of these comments, APTA recommends that CMS make the following clarifications in the final rule:

1) CMS should provide more information about the planned site visits (for example, who will be conducting them, their expected frequency, and what the focus of such site visits might be).
2) CMS should clarify the different roles of ACO participants and providers/suppliers when being audited because of their activity in the ACO and other audits conducted under other Medicare programs such as Recovery Audit Contractors (RACs), the Comprehensive Error Rate Testing (CERT) program, and Zone Program Integrity Contractors (ZPICs).
3) CMS should clarify that ACO participants and ACO providers/suppliers will not be unfairly targeted for audits by MACs, RACs, ZPICs, and other Medicare and state entities due to their affiliation with an ACO.
4) CMS should clarify that an ACO’s negative program integrity status does not affect ACO participants and ACO providers/suppliers’ program integrity status for Medicare fee-for-service claims submitted for services delivered outside of the ACO.

New Program Standards during the 3-Year Agreement

APTA is also concerned about CMS’s proposal to prohibit the addition of any ACO participants during the three-year agreement. Specifically, CMS states that:

“Whenever an ACO reorganizes its structure, we must determine if the ACO remains eligible to participate in the Shared Savings Program. Since an ACO is admitted to the program based on its application, adding ACO participants during the course of the 3-year agreement may deviate from its approved application and jeopardize the ACO’s eligibility since the ACO would differ from its approved application and could be subject to further antitrust review. Changes such as this may result in termination of the 3-year agreement and forfeiture of the 25 percent withhold of shared savings earned by the original ACO participants. We therefore propose that the ACO may not add ACO participants during the course of the 3-year agreement. In order to maintain flexibility, however, we propose that the ACO may remove ACO participants (TINs) or add/subtract ACO providers/suppliers (NPIs).”

While we understand the rationale offered by CMS, we would urge the Agency to create a process that would give some flexibility in this area. We believe that the proposed policy is too strict and does not allow the ACO to make structural changes that may be integral to meeting the mandates of the MSSP and the needs of Medicare beneficiaries. ACOs need more flexibility to add participants (for example, to compensate for the loss of participants or to better meet the needs of
their assigned Medicare beneficiaries). In addition, given the expected tight deadlines for filing ACO applications, organizations may not have time to enter into agreements with all the participants they would ultimately desire to include in their organization. For example, while an ACO might be expected to focus its energies on identifying its primary care physicians, it might not have time to conclude agreements with other providers and suppliers, such as physical therapy practices. At the very least, we recommend that CMS create a process where ACOs could request an amendment to their MSSP agreement to add an ACO participant if demonstrated that the addition of the ACO participant is for the benefit of patient care and does not violate anti-trust laws regarding market dominance. We are not convinced, however, that an ACO’s desire to add a single physical therapy practice should trigger some burdensome application process, and thus the process we are suggesting here might be reserved for selected circumstances, such as the addition of a large primary care physician practice.

**Considerations for Providers Operating Outside of the ACO**

CMS states throughout the proposed rule, that participation in the MSSP is voluntary for professionals and patients and those patients may obtain Medicare-covered services from any Medicare provider or supplier regardless of their assignment to an ACO. **APTA strongly supports this provision and strongly believes that the decision to participate or not to participate in an ACO should be solely decided by the patient and/or the provider/supplier.** Both entities must make decisions free of coercion or pressure from outside influences.

Specifically, to mitigate cost shifting in the Medicare program to patients outside of ACOs, CMS is considering prohibiting ACOs and the participants from conditioning participation in the ACO on referrals of Federal health care program business that the ACO or its ACO participants know or should know is being provided to beneficiaries who are not assigned to the ACO.

**APTA strongly recommends that CMS establish this prohibition in the final rule and clearly emphasize that any behavior that seeks to impede referrals or care by professionals who are not participating in the ACO will be greatly monitored and penalized.** CMS should collect and analyze claims data not only for ACOs in a given area but it should also compare the claims data of the ACO to that of Medicare enrolled providers and suppliers in the same area during the same time period who are not participating in the ACO. These data should be analyzed not only for utilization comparisons and outcomes, but also to detect aberrant billing patterns that signal abusive or fraudulent activities. In addition, CMS should ensure that beneficiary educational materials regarding ACOs clearly inform beneficiaries that there are no barriers to their receiving care outside of an ACO and that ACOs are not allowed to impose any such barriers.
Second, CMS should re-emphasize in its correspondence to ACOs that patients have the right to receive care from providers and suppliers who are not a part of the ACO. In this correspondence, we urge CMS to make it clear that ACOs do not impede or restrict these providers and suppliers from obtaining access to medical records and other information that is needed to treat patients assigned to the ACO in accordance with the Health Insurance Portability and Accountability Act (HIPAA) of 1996\textsuperscript{13} privacy and security laws.

Last, APTA recommends that all providers and suppliers, regardless of their involvement in the ACO should be notified that an ACO is forming in their area. This notification should give a detailed explanation of the MSSP ACO requirements and contact information in case providers and suppliers have questions.

In closing, APTA thanks CMS for the opportunity to provide comments on the Medicare Shared Savings Program: Accountable Care Organizations proposed rule. As stated earlier, physical therapists are committed to providing care to Medicare beneficiaries through integrated models of care such as ACOs. APTA looks forward to working with the Agency to ensure that ACOs are structured in a manner that is patient-centered, provides high quality care and seamlessly coordinates care throughout the health care continuum. 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,

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RSW: rdd

\textsuperscript{13} Pub.L. 104-191