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May 31, 2011

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1345-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically to <http://www.regulations.gov>

Re: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations.

File Code: **CMS-1345-P (Posted April 7, 2011)**

Dear Administrator Berwick:

The American Nurses Association (ANA) welcomes the opportunity to offer comments on the proposed rule that would implement section 3022 of the Affordable Care Act (ACA) of 2010, containing provisions relating to Medicare Accountable Care Organizations (ACOs).

The ANA is the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses (RNs), the single largest group of health care professionals in the United States. We represent RNs in all roles and practice settings, through our state and constituent member nurses associations, and affiliated nursing specialty organizations.

Summary of Comments

ANA supports the proposed rule's vision of a patient-centered care delivery model that improves quality of care while seeking greater efficiencies and savings. Assessing the components of quality and cost together holds the promise to address some of the most intransigent obstacles to better patient care and resource allocation in our current health care "non-system," because it establishes a new measure of accountability – value.

The proposed rule for Accountable Care Organizations (ACOs) details a complex series of mechanisms and controls that CMS has designed to meet the requirements of the Affordable Care Act (ACA) provision on shared savings in Medicare. Understandably, and as the Background to the proposed rule notes, ACOs may have an incentive to treat Medicare beneficiaries and commercial insurance beneficiaries using the same rules, to minimize dissonance and redundant costs in their clinical and business practices. Therefore, ANA believes

that it is more important than ever for the regulations at hand to accurately portray the essential variables in establishing value in care delivery.

From this perspective, ANA believes that CMS has largely neglected to include the contributions of nursing in its provisions and parameters describing integrated practice in general, and the ACO in particular. Care coordination is a building block on which much of the ACO quality improvement and cost control provisions are built. And care coordination is a core competency for the nursing profession; it is what nurses do. Yet the proposed rule largely disregards the contributions of professional nursing in both clinical services and patient management, and as a result, loses the opportunity for real cost savings. Lastly, this oversight has the potential to ignore the needs of the many Medicare beneficiaries who call nurse practitioners (NPs), clinical nurse specialists (CNSs) and certified nurse-midwives (CNMs) their “primary care provider.” This can create confusion that threatens patient choice and the patient-provider relationship.

Registered Nurses across the country have been at the forefront of testing many models for improving care quality and coordination from a patient-centered perspective that is, and has always been, at the heart of nursing practice. Nurses have met with success after success in designing and implementing care coordination protocols and practices that improve patient outcomes and save money. ANA’s comment to the proposed ACO regulation addresses some of the ways in which these “lessons learned” might help CMS design ACOs to achieve their desired purpose.

The various questions posed by CMS throughout the Background section reveal a strong desire from CMS to receive the feedback of various constituencies with the expertise and experience to suggest improved ways to approach these complexities. ANA herein offers a series of recommendations reflecting the rich resources the nursing profession can provide in filling in some of these areas of uncertainty. Specifically, ANA recommends, and discusses in detail, modifications in the proposed rule to address the following:

1. Registered Nurses provide care coordination and patient-centered care as a core professional nursing standard of practice
2. Registered Nurses’ innovations in care delivery models offer principles and experience to guide successful care coordination and quality improvement, particularly with high risk and vulnerable populations
3. Registered Nurses are integral to quality of care improvement and their contributions should be recognized and measured
4. Nurse practitioners, clinical nurse specialists, and certified nurse midwives are essential primary care providers
5. Financial and systemic incentives should be required for care coordination to assure that it is properly designed and implemented by qualified healthcare professionals with experience in care coordination.

Nurses, side by side with our patients, daily battle the inefficiencies and unresponsiveness of our current non-system. We are deeply committed to help innovative delivery systems succeed. By failing to recognize and reward nurses’ role in improving both quality outcomes for patients and

efficient resource allocation within the ACO, CMS has effectively created a blind spot obscuring what could otherwise be part of a progressive transformation of the healthcare system.

Promoting and Supporting Coordination of Care and Patient-Centeredness

Background: Registered Nurses (RNs) provide care coordination and patient-centered care as a core professional standard of nursing practice. RNs have a proven track record in developing and implementing principles and processes that lead to improved patient outcomes and, in some instances, greater cost savings.

The ACA requires an ACO to “define processes to ... coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.” Coordination of care is described as involving strategies to promote, improve and assess integration of care among providers and throughout episodes of care. Compliance with the requirement may be achieved using various strategies. The proposed regulation offers several examples, which include: predictive modeling to anticipate care needs; utilization of case managers in primary care offices; a transition of care program that includes clear guidance and instructions for patients, families and caregivers; remote monitoring, telehealth, and the establishment of health information technology including electronic health records and electronic health information exchange.

Issue: Qualifications and skills of successful care coordinators

Comment to CMS: ANA recommends that CMS adopt the National Coalition on Care Coordination¹ definition of care coordination as “... a person-centered, assessment-based, interdisciplinary approach to integrating health care and social support services in a cost-effective manner in which an individual’s needs and preferences are assessed, a comprehensive care plan is developed, and services are managed and monitored by an evidence-based process which typically involves a designated lead care coordinator” [Section 425.4, “Definitions,” p. 19641]. The key to this definition is *a health professional who serves as the lead care coordinator*. The care coordinator should be a health professional from any of several different disciplines for most patients; however, for many, a registered nurse is often the best care coordinator.

Rationale: ANA endorses use of a care coordinator to assure that the needs of patients are identified and met, and to support providers. A care coordinator should be a health professional from any of several different disciplines for most patients; however, for many, a registered nurse is often the best care coordinator. Registered nurses (RNs) are educated to provide care coordination and have the knowledge, skills and competencies to serve in this role. Care coordination is one of the standards of professional nursing practice to which *all* RNs are held.² The care coordination competencies of the RN include:

¹ National Coalition of Care Coordination. (2010). Implementing care coordination in the affordable care act.

² American Nurses Association. (2010). Nursing: Scope and standards of practice, 2nd edition. Silver Spring, MD: American Nurses Association.

- the ability to organize the components of the care plan,
- management of the patient's care to maximize independence and quality of life,
- facilitating communication with the patient, family and members of the health care system, and
- serving as an advocate for the delivery of dignified care by the inter-professional team.

A report on best practices in care coordination to the (former) Health Care Financing Administration recommended use of registered nurses with bachelor degrees as care coordinators.³ In 14 of 15 sites included in the Medicare Coordinated Care Demonstration, registered nurses were used as care coordinators. The only two sites that were successful in reducing hospital readmissions and expenditures relied on registered nurses with bachelor degrees for coordination of care.⁴

Research indicates that nurses are particularly important in the role of care coordinator for high risk, frail elders and other patients with significant health care needs. In the proposed rules, CMS has defined “at risk” as a beneficiary who [Section 454.4; p. 19641]:

- (1) Has a high risk score on the CMS–HCC [hierarchical condition category] risk adjustment model;
- (2) Is considered high cost due to having two or more hospitalizations each year;
- (3) Is dually eligible for Medicare and Medicaid;
- (4) Has a high utilization pattern; or
- (5) Has had a recent diagnosis that is expected to result in increased cost.

Many Medicare patients who will be enrolled in ACOs will have diabetes, a condition that can implicate multiple elements of the “at risk” definition. A systematic review of the literature identified that nurses were highly effective as care coordinators for patients with diabetes.⁵ Many Medicare patients will also have heart failure, comprising another “at-risk” group whose care often results in costly admissions and readmissions to the hospital,⁶ which can be prevented by effective care coordination.

³ Chen, A., Brown, R., Archibald, N., Aliotta, S., Fox, P.D. (2000). Best Practices in Coordinated Care. Mathematica Policy Research, Inc. Report. Retrieved from http://www.cms.gov/DemoProjectsEvalRpts/downloads/CC_Full_Report.pdf

⁴ Peikes, D., Chen, A., Schore, J., Brown, R. (2009). Effects of care coordination on hospitalization, quality of care, and health expenditures among Medicare beneficiaries. *Journal of the American Medical Association*, 301(6), 603-618.

⁵ Ingersoll, S., Valente, S.M., Roper, J. (2005). Nurse care coordination for diabetes: A literature review and synthesis. *Journal of Nursing Care Quality*, 20(3), 208-214.

⁶ Koehler, F., Winkler, S., Schieber, M., Sechtem, U., Stangl, K., Bohm, M., . Anker, S.D. (2011). Impact of remote telemedical management on mortality and hospitalizations in ambulatory patients with chronic heart failure: The telemedical interventional monitoring heart failure study. *Circulation*, March 28 epub ahead of print.

Issue: Transitions in Care requirements should provide more specific guidance

Comment to CMS: ANA recommends that additional, specific guidance be included in section 425.5 (d)(15)(ii)(B)(5) of the proposed rule, consistent with the requirements of ACA section 3026 (“Community Based Transitional Program”), regarding the mechanisms in place for coordination of care as part of the required elements for patient-centered care in an ACO [p.19645].

Rationale: The use of transitional care has proven to be very effective in reducing readmissions, increasing the time between discharge and readmission or death, and in reducing health care costs. The transitional care model is a vital component of care coordination directed by an advanced practice registered nurse.⁷

ANA is pleased to note that transitions in care among providers, whether inside or outside the ACO, are an essential principle for patient-centered care in the proposed rule. [p. 19548; proposed rule Section 425.5(d)(15)(ii)(B)(5)(i), p.19645] The statutory inspiration for its inclusion in the ACO proposed rule appears to be Section 3026 of the ACA, “Community Based Transitional Program,” in the same Part III of Title III in which the “Medicare Shared Savings Program” section appears (“Encouraging Development of New Patient Care Models”). ACA Section 3026 lists those interventions which improve the likelihood of successful transition for high-risk Medicare beneficiaries between a hospital and a community-based organization.

CMS should likewise include these interventions to provide further guidance to ACOs regarding strategies for care coordination and patient-centeredness [pp. 19547-8; proposed rule Section 425.5(d)(15), p. 19645]. Currently, the proposed rule calls for processes for transition of care to be in place but provides little guidance as to successful principles for implementation, based on a concern that the requirement will be overly prescriptive. Yet ANA believes evidence-based protocols should be included in the NPRM to better establish expectations for ways in which ACOs can meet required principles. While there may be some overlap of these interventions with the NPRM’s Quality Measures 9, 10 and 11, regarding Coordination of Care/Transitions, the Section 3026 elements that might be adopted now or in future rulemaking are:

“(i) Initiating care transition services for a high-risk Medicare beneficiary not later than 24 hours prior to the discharge of the beneficiary from the eligible entity;

(ii) Arranging timely post-discharge follow-up services to the high-risk Medicare beneficiary to provide the beneficiary (and, as appropriate, the primary caregiver of the beneficiary) with information regarding responding to symptoms that may indicate additional health problems or deteriorating condition;

(iii) Providing the high-risk Medicare beneficiary (and, as appropriate, the primary caregiver of the beneficiary) with assistance to ensure productive and timely interactions between patients and post-acute and outpatient providers;

⁷ Naylor, M.D., Brooten, D.A., Campbell, R.L., Maislin, G., McCauley, K.M., Schwartz, J.S. (2004). Transitional care of older adults hospitalized with heart failure: A randomized controlled trial. *Journal of the American Geriatric Society*, 52(5), 675-684.

(iv) Assessing and actively engaging with a high-risk Medicare beneficiary (and, as appropriate, the primary caregiver of the beneficiary) through the provision of self-management support and relevant information that is specific to the beneficiary's condition; and

(v) Conducting comprehensive medication review and management (including, if appropriate, counseling and self-management support)."

CMS has requested comments on whether additional patient-centered criteria should be added to the proposed rule [p.19549]. ANA recommends that the change proposed above be reflected in section 425.5 (d)(15)(ii)(B)(5) of the rule regarding the mechanisms in place for coordination of care as part of the required elements for patient-centered care [p.19645]. In addition to providing necessary guidance, the inclusion of these criteria would enhance much needed coherence among CMS programs created by the ACA. As Dr. Mary Naylor has discovered in her seminal research (upon which the ACA provision is based), advanced practice registered nurses in the role as directors of care coordination during care transitions offer the potential for successful outcomes and reduced health care costs.⁸

Issue: Successful Models of Care Coordination and Registered Nurses

Comment to CMS: ANA recommends that CMS look to the examples of innovative nursing-led models of care delivery as a resource or guidance for ACOs for improving patient outcomes while controlling or decreasing costs.

Rationale: The American Academy of Nurses (AAN) has developed the Edge Runners program to highlight care models and interventions that improve clinical and financial outcomes. Many are longstanding and provide care to large numbers of Medicare beneficiaries. Dozens of successful initiatives in a variety of care settings are described by the Edge Runners program, "Raise the Voice."⁹ The following are but a few examples:

Evercare, established in 1987, is a model of care that uses nurse practitioners (NPs) or care managers at the center of an interdisciplinary team to overcome fragmentation of care and improve health outcomes. In addition to developing personalized plans of care, the services include coordination of care among the team members. NPs also provide direct care to nursing home patients making visits as often as necessary. An Evercare program in Texas between February 2000 and January 2002 saved the state approximately \$123 million.

On Lok Senior Health Services was developed in 1971 by Jennie Chin Hansen, R.N., M.S., F.A.A.N (current MedPAC Commissioner and CEO of the American Geriatric Society, former AARP President) as a day program for seniors. In the 1980s it was expanded and became a national model as an alternative to nursing home care. Nurses

⁸ Ibid.

⁹ American Academy of Nurses. (2011). Edge Runner Directory. Retrieved from <http://www.aannet.org/custom/edgeRunner/index.cfm?pageid=3303&showTitle=1>

are part of the interdisciplinary team that provides comprehensive services. This program was the prototype for the Program for All-Inclusive Care for the Elderly (PACE) which became a permanent part of Medicare in 1997. A majority of states have exercised the option to offer PACE programs under Medicaid.

The Senior ASSIST (Assisting Seniors to Stay Independent through Services and Teaching) program uses nurses with expertise in geriatric care as care coordinators to work with frail elders with multiple health problems to continue to live in their homes and avoid hospitalizations. In the program's first ten years, 21,000 home visits were made to 503 clients who in their first six months of care experienced a 63% decrease in hospitalizations, a 46% decrease in ER visits and a 62% cost savings.

Issue: While the requirement for ACOs to create systems to identify high-risk individuals and develop individualized care plans for targeted population groups is laudable, it should provide additional guidance on the minimum elements that such a plan should contain to ensure patient-centeredness. [p.19645, section 425.5(d)(15)(ii)(4)]

Comment to CMS: CMS's requirement for individualized care plans calls for the following bulleted features. Each of these is accompanied by ANA's recommendations for specific elements to be added to the rule itself. If CMS determines that the inclusion of these more specific elements would be too prescriptive, it should include and develop these elements, at a minimum, in a subsequent CMS "Guidance."

- Integration of community resources to address individual needs
 - whether and when home health or other healthcare agency personnel will be making a home visit
 - recommended, scheduled, and available social service activities
- Promotion of improved outcomes for, at a minimum, high-risk and multiple chronic condition patients and, as appropriate, other patients with chronic conditions
 - preventive care and services promote optimal health and to prevent additional health problems
 - patient education
 - prescribed medications and their proper usage
 - signs and symptoms that should trigger a call to the provider
 - recommended and scheduled health care appointments
 - self-care monitoring such as daily weight or blood glucose testing
- Tailoring of plans to the beneficiary's physical and mental health, as well as psychosocial needs
 - non-pharmacologic therapeutic care such as physical or occupational therapy
 - dietary and lifestyle considerations including recommendations regarding alcohol use and tobacco cessation, if applicable
 - adequacy and safety of home environment
 - current relationships and access to social interactions
- Accounting for beneficiary preferences and values
 - existence of advance directives
 - preferences regarding pain and palliative care
 - use of complementary and alternative treatments, as applicable

- cultural, ethnic, socioeconomic and personal preferences
 - consideration of the patient's literacy, health literacy and numeracy
- Identifying community and other resources to support the beneficiary in following the plan.
 - availability of family and other caregivers
 - names, addresses and phone numbers of the patient's pharmacy(ies), providers, nearby hospitals and community resources (such as Meals on Wheels or senior centers)
 - tobacco cessation programs, and substance abuse recovery resources, if applicable
 - transportation contacts, if applicable

Rationale: ANA is pleased that the proposed rule builds on the ACA's recognition of the special needs of high-risk beneficiaries and those individuals with chronic conditions. The requirement for individualized care plans, in particular, can help reduce emergency department visits and readmissions, two costly and avoidable consequences of inadequate monitoring or follow-up care. The monitoring and evaluation of treatment response and outcomes can provide essential information on whether the intensity of care is appropriate and how collaborative care might adjust services to meet the changing needs of the beneficiary. The care plan, as well as continued monitoring and evaluation of the beneficiary's status, should be carried out by qualified health professionals. Registered nurses are best prepared to work with high-risk patients and patients with targeted chronic health conditions, their caregivers and the interprofessional team to develop the individualized care plan.

The rule proposes that the plan of care should be tailored to the beneficiary's health and psychosocial needs, account for beneficiary preferences and values, and identify community and other resources to support the beneficiary. The proposed rule would require that an ACO submit a description of its individualized care program along with a sample plan of care. It also is required for the ACOs to define other at-risk populations.

There is no one plan of care that can be recommended as a model; however, there are specific elements of the plan that need to be included as a minimum set. This assures a comprehensive approach to the plan, allowing it to be used in a meaningful way by the patient, his or her caregiver, and the team of providers. The care plan would need to be individually evaluated for those elements beyond these minimum requirements to assure that the needs and preferences of each beneficiary are truly met. The monitoring and evaluation of the beneficiary's status should be a continuing requirement of any care plan in order to assess effectiveness of care and resource allocation.

Issue: Use of Health Information Technology and Telehealth/Remote Monitoring in the Coordination of Care

Comment to CMS: ANA recommends that Section 425.5 (d)(15)(ii)(B)(5), regarding a mechanism in place for coordination of care to satisfy "patient-centeredness" requirements, be modified as follows:

Delete the parenthetical phrase “(for example, via use of enabling technologies or care coordinators)” and replace it with: “(for example, designation of a qualified care coordinator who can communicate directly and through appropriate technologies to provide timely referrals, decision-making, counseling, and other services, as needed.)” [p. 19645]

Rationale: The proposed ACO rule refers several times to the use of electronic enabling technologies and exchange of information as strategies for care coordination. ANA recognizes that health information technology is central for receiving real time feedback at the point of care and for avoiding medication errors.

Yet it is also important to recognize that electronic technologies are tools to support care coordination; they do not, in themselves, constitute “care coordination.” ANA recommends that CMS more fully recognize the necessity of care coordinators who can offer the cognitive decision-making and counseling skills to implement care coordination with the assistance of helpful tools such as electronic information exchange.

Remote electronic monitoring is among those electronic technologies discussed in the Background section of the proposed rule. There are unanswered questions about the use of remote electronic monitoring, and several examples suggest that this approach should be used selectively. Systematic reviews and a study of this strategy conclude that the technology holds promise and more research is needed. The effectiveness of remote monitoring devices may depend largely on nurses or other qualified health care personnel who follow up with patients with, for example, phone calls. Reliance on technology alone is not sufficient; a healthcare professional with appropriate judgment, experience and skills is needed to assess the patient’s condition and changing needs in light of the information provided by technology.

Health information technology can facilitate the work of care coordination, however this also requires the interoperability of systems. Depending on the number of ACO participants who are able to meet EHR “meaningful use” standards, this may not be a problem within an ACO that is an integrated system. Since beneficiaries will have the option to seek care outside an ACO, though, a lack of interoperable information systems will demonstrate the unfortunate consequence of confusing the technological tools with the actual work of care coordination.

Issue: Freedom for Patients to Seek Care from Providers/ Suppliers Outside the ACO

Comment to CMS: ANA supports the proposed rule’s provision that would prohibit the ACO from developing any policies that would restrict a beneficiary’s freedom to seek care from providers and suppliers outside the ACO.

Rationale: CMS is proposing to prohibit the ACO from developing any policies that would restrict a beneficiary’s freedom to seek care from providers and suppliers outside the ACO. ANA fully supports this proposed provision. This allows beneficiaries to continue to receive care from advanced practice registered nurses, physicians, and a host of other qualified healthcare professionals who may not be part of the ACO. This is essential to promoting continuity of care, which is crucial to the goal of coordinating care and diminishing fragmentation. For example, a patient may be assigned to an ACO based on a patient’s visits

to an internist; however, the patient may have been receiving the bulk of his or her primary care from a nurse practitioner who is not part of the ACO. The proposed provision will allow the patient to continue to receive care from the NP with whom there is an established relationship.

Issue: Documentation of various ACO requirements may become burdensome and divert healthcare professionals from delivering care.

Comment to CMS: The amount of documentation required should be carefully balanced. What is necessary to validate care should not divert health professionals and care coordinators from the actual delivery of care. CMS should also solicit feedback on the utility and burden of the required documentation after the regulation has been in effect for a period of time.

Rationale: CMS asks for comments regarding “whether these criteria [for patient-centeredness] are burdensome and whether they might create disincentives to participate or make it difficult for small entities to participate in the program” [p. 19549]. ANA believes that CMS has identified a serious question that is equally applicable to small and large entities. The amount of documentation required should be carefully balanced between what is necessary to validate care while not diverting care coordinators from the actual delivery of care. A secondary analysis of nurse case management that was part of the Medicare Coordination of Care Demonstration identified that patients averaged 60 minutes of case management a month, almost half of which the nurses used to document case management activities (Oliva, 2010).¹⁰ ANA has concerns that registered nurses who are already overburdened with direct patient care responsibilities will see their workloads increased due to additional documentation requirements for ACO patients. While some of this is necessary and unavoidable, ANA asks that CMS continue to carefully consider the consequences of additional administrative burden as it may affect direct patient care. To examine this, CMS should consider soliciting comments on the utility and burden of the required documentation after the regulation has been in effect for a period of time.

Quality of Care Issues

Issue: Leadership pertaining to quality issues within the ACO is exclusive to physicians and does not permit appropriately qualified health professionals, including registered nurses, to assume such roles.

Comment to CMS: ANA recommends that Section 425.5(d)(9)(iii) be amended to read: “Clinical management and oversight must be managed by a full time senior-level ~~medical~~ director who is physically present on a regular basis in an established ACO location, and who is a ~~board-certified physician and~~ qualified healthcare professional licensed in the State in which the ACO operates.”

¹⁰ Oliva, N.L. (2010). A closer look at nurse case management of community-dwelling older adults: observations from a longitudinal study of care coordination in the chronically ill. *Professional Case Management*, 15(2), 90-100.

ANA further recommends that Section 425.5(d)(9)(v) be amended to read: “(v) A ~~physician-directed~~ quality assurance and process improvement committee must oversee an ongoing action-oriented quality assurance and improvement program....” [p.19644]

Rationale: Section 1899(b)(2)(F) of the ACA requires ACOs, as a requirement for eligibility, to “have in place a leadership and management structure that includes clinical and administrative systems.” This is followed by section (G), which adds: “The ACO shall define processes 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 such enabling technologies.” These two sections appear to be the basis for the Secretary’s requirement for an ACO’s application to include physician-led “clinical management and oversight” and a “physician-directed quality assurance and process improvement committee.”

The ACA does not include a statutory provision requiring physician leadership of ACO clinical management and oversight, nor for quality assurance and process improvement. The inference made by the proposed regulatory provision -- that a physician is automatically more qualified than other healthcare professionals to lead such processes -- is not supported by research or in practice.

The health care quality literature, clinical practice and managerial evidence support the role of registered nurses, including APRNs, as highly qualified professionals to lead clinical management and oversight committees and other quality assurance and process improvement mechanisms within institutions and organizations. The Institute of Medicine, in its 2011 report “The Future of Nursing: Leading Change, Advancing Health,” recommends that nurses be full partners with physicians and other healthcare professionals and that nurses should act as leaders in implementing systems such as ACOs.¹¹ This is true across the spectrum of institutions and organizations regardless of size, geographic location, patient demographics, and other defining characteristics.

Nurses already are at the helm of a multitude of just such programs. Examples include Julianne Morath, RN, MS, Chief Quality and Patient Safety Officer at the University of Vanderbilt Medical Center; and Tamara Merryman, RN, MSN, FACHE, Chief Quality Officer at the University of Pittsburgh Medical Center. Further, nurse leaders within the US Department of Health and Human Services itself, as well as other federal departments and agencies, have directed similar quality assurance programs and led clinical management and oversight within various institutions earlier in their careers, as well as providing national leadership in their current posts.

CMS notes in the proposed rule’s Background section that it would, in the application process, consider alternative “innovative ACO leadership and management structures” to meet the various described goals. It includes the example of ACOs that do not have a physician-led quality assurance and process improvement committees. ANA recommends that the rule be expanded so that management and oversight processes/bodies led by appropriately qualified healthcare professionals would meet ACO eligibility requirements

¹¹ Institute of Medicine (IOM). 2011. *The Future of Nursing: Leading Change, Advancing Health*, Washington, DC: The National Academies Press.

without requiring an implicit exception. It is not in the best interests of patients to limit leadership of clinical management and oversight or quality assurance and process improvement committees solely to physicians and ANA requests that the regulation be modified to include other qualified professionals.

Issue: Patient-centeredness principles in the proposed rule measure only physicians' clinical or service performance. The rule should also include measures of nursing processes and outcomes to seize a crucial opportunity for improving care and service over time.
[Section 425.5(d)(15)(ii)(B)(9), p. 19645]

Comment to CMS: ANA recommends that Section 425.5(d)(15)(ii)(B)(9) be amended to read: “(9) Internal processes in place for measuring clinical or service performance by ACO professionals and registered nurses across the practices, and using these results to improve care and service over time.” [p.19645]

Rationale: The proposed rule's patient-centeredness principles appropriately recognize that the performance of care providers must be measured in order to provide opportunities to analyze and compare outcomes with the purpose of improving future care delivery. Only physicians' work is measured, though, despite registered nurses' integral clinical and service functions within an ACO that bear directly on the quality and safety of care, as well as the patient's experience of care. These contributions are ignored; however, this oversight can be ameliorated by using existing data collection efforts specifically aimed at measuring nursing performance.

ANA's National Database of Nursing Quality Indicators (NDNQI®) is a nationally recognized program that collects and evaluates unit-specific nurse-sensitive data from hospitals in the United States and abroad. Participating facilities receive unit-level comparative data reports to use for quality improvement purposes.

As of April, 2011, NDNQI® has been adopted by almost 2000 hospitals in the United States and internationally. This is approximately one-third of American hospitals where nurse-specific data is already being collected and analyzed to permit performance assessment and improvements in patient care. Furthermore, CMS's Hospital Inpatient Quality Reporting (IQR) Program (formerly the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU)) now includes a focus on measuring nursing quality. Beginning in FY2010, the CMS requirement includes hospital reporting on whether or not nurses participate in a systematic clinical database registry for nursing-sensitive care. Participation in the ANA's NDNQI® database satisfies CMS's reporting requirement.

Given that there are widely adopted and validated clinical measures that directly assess nursing-specific care at the unit level, the inclusion of a measuring requirement for registered nurses in ACO hospitals will contribute substantially to a better understanding of how care can be improved, while not imposing a significant burden on ACOs to collect this data. (More information about NDNQI® is available at <https://www.nursingquality.org>.)

Issue: Measures to Assess the Quality of Care Furnished by an ACO [pp. 19648, et seq.]

Comment to CMS: ANA believes that the number of quality measures is too burdensome and should be reduced. A smaller measures set will permit ACOs to intensify their initial attention on the most crucial aspects of improving care that provide the greatest potential for savings. It will also promote ease of reporting and permit both ACOs and CMS to acclimate to new systems.

The most important patient-centered quality indicators should be more carefully selected and retained as a core set. ACOs could also select from a CMS-developed set of voluntary measures to reflect the needs pertinent to their specific patient populations. As an incentive for ACOs to volunteer for added measures, CMS could offer an additional increment of shared savings linked to the achievement of quality benchmarks and savings attributable to the added measure(s).

Rationale: CMS has selected 65 quality measures in 5 domains. ANA believes this requirement will create a significant disincentive for groups that might otherwise apply for ACO status. A reduced number of measures will allow ACOs, as they implement care delivery and systems changes, to concentrate on a few carefully selected core elements that hold the potential for the greatest quality improvements and savings. As the Shared Savings program evolves along with its ACO partners, it is reasonable to increase the number of measures as both CMS and ACOs learn and acclimate to new requirements and systems.

To accommodate those ACOs with more experience or that serve greater numbers of at-risk beneficiaries, it might make sense to offer an added set of optional measures beyond the smaller core set. An ACO might be enticed to volunteer for the additional measures if the result could be an increase in shared savings based on success in improving quality and reducing costs attributable to that measure(s).

CMS has made an effort to align existing measures where possible, yet this does not address the problem of aligning multiple reporting systems among ACO participants. There is a significant potential for interoperability problems among different providers and different systems that the proposed rule is seeking to merge. ANA does not believe it is reasonable to hold ACOs accountable for problems that CMS anticipates with implementation and has clearly acknowledged in the NPRM. A phased-in process might be more realistic to account for the establishment of consolidated practice management systems.

Another question regarding alignment involves how to treat hospitals and other providers who are subject to pay-for-value standards that are already in place. Are these providers, in essence, penalized or rewarded doubly by imposing ACO evaluation on top of existing incentive programs?

Comment to CMS: The proposed rule is vague about how risk adjustment would take into account highly impacted populations who might make improvements in health status but still not meet a measure's optimal requirements.

Rationale: ANA is concerned about uncontrollable factors that contribute to whether a provider can achieve a measure. Measures based on survey and claims data are fairly straightforward to evaluate. However, a patient-centered system must acknowledge the patient's right to decide whether he or she will follow recommendations of health care professionals, based on cultural, financial or other personal preferences. What happens when a patient chooses a course of care different than what is recommended by the provider? In Measure #35, for example, which is subject to "all-or-nothing" scoring, does the provider fail because the diabetic patient uses tobacco?

Additionally, even though a provider recommends evidence-based treatment and the patient adopts the recommendations, there are times when the patient still doesn't reach the standards set by a measure. It is unclear how a measure might account for an individual's improvement in health status that does not rise to the quality standard. An example might be when the hemoglobin A1C of a diabetic patient improves from 12 to 9.5. This would be considered a significant improvement yet not achieve the standard setting diabetics' hemoglobin at A1Cs <8 (Measures #35 and #36). The proposed rule is vague about how risk adjustment would take into account highly impacted populations who might make improvements but still not meet a measure's optimal requirements.

Comment to CMS: ANA recommends that the scoring methodology should be weighted to reflect the significance of Domains #1 and #2, Patient/Caregiver Experience and Care Coordination, as foundations for success in improving process and outcomes. Furthermore, ANA suggests that CMS include the NQF Measure Application Partnership (MAP) among its sources for guidance in prioritizing measures.

Rationale: Patient/caregiver satisfaction with their care experience and the coordination of that care are fundamental to the success of patient-centered care. The better the experience with his or her providers and the system, the more likely the patient will be to engage and participate in the care process, which leads to better outcomes. The goal of ACOs is to provide truly patient-centered care. Consequently it is essential to acknowledge patient/caregiver satisfaction and care coordination as the crucial *links* between the process of care and improved outcomes. In evaluating an initial core measure set, CMS should emphasize these domains #1 and #2 as fundamental to the success of the other three domains.

Comment to CMS: As an additional criterion for selecting process and outcomes quality measures, CMS should evaluate whether a potential measure relates across the care continuum.

Rationale: The selected quality measures do not allow for the evaluation of quality across the care continuum, such as in the post-acute and long-term care settings. It is essential to assure that the quality of care is adequately evaluated regardless of the setting in which the beneficiary receives care. The quality of care provided by a "primary care health home" includes the evaluation of those community and home based services linked to the primary care provider's referrals. For example, while the home health care and long term care settings measure a patient's functional status, there is no functional status measure reported

on Hospital Compare. Currently hospital readmissions might be considered an imperfect proxy for independently evaluating functional status, but such loose inferences should be replaced with consistent measures. To remove this continuity factor from CMS' deliberations undermines the basic concepts of coordinated interdisciplinary team care that is the essence of the ACO model.

In some cases, such measures would be more suitable for some ACOs than others, based on their populations' characteristics. To account for this, it may be appropriate to place the measures relevant to the continuum of care in the "voluntary," rather than "core" measure set, as the Shared Savings program is rolled out. ANA acknowledges that there exist current gaps in measuring effective care across the care continuum; thus, integration of measures developed in the future should be part of CMS's ongoing measure evaluation process.

Comment to CMS: ANA recommends that quality measures reflect the interprofessional composition of the ACO, and in particular the contributions of nurses. ANA recommends that CMS consider augmenting or consolidating Measures # 2 and #4, in Domain 1 "Patient/Caregiver Experience," by using the Hospital CAHPS® and CAHPS Home Health Care Survey. In addition, ANA recommends adding the existing supplemental questions to the Clinician/Group CAHPS Survey that evaluate the care of nurse practitioners.^{12, 13} These surveys provide a more complete picture of the patient's care experience, collecting measure-specific multidisciplinary data on which to base future improvements.

Rationale: The selected quality measures do not reflect the interprofessional nature of an ACO and in particular the contributions of nurses who will be essential to the delivery of care in hospitals and across the care continuum. There is no existing measure to evaluate how well the physician and registered nurse collaborate. CMS can look to certain systems as proxies until such a measure is developed. This will require a modification of the proposed measures for the Patient/Caregiver Experience domain.

The proposed rule's Patient/Caregiver Experience domain utilizes the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Clinician & Group Survey [Section 425.5(d)(15)(B)(1); p. 19645]. This survey on which the proposed rule relies does not assess care coordination by nurse practitioners, clinical nurse specialists or registered nurses, which is included in the hospital and home health care surveys.

The proposed patient/caregiver experience measures do not assess care or communication by nurses. ANA recommends adding the Hospital CAHPS (H-CAHPS) quality measures to

¹² **H-CAHPS** six composites summarize how well nurses and doctors communicate with patients, how responsive hospital staff are to patients' needs, how well hospital staff help patients manage pain, how well the staff communicates with patients about medicines, and whether key information is provided at hospital discharge.

CAHPS Home Health Care Survey focuses on patients who receive skilled home health care services (e.g., care coordination by nurses) from Medicare-certified Home Health Agencies (HHAs). Skilled services refer to health care services provided by nurses and therapists including physical, occupational, and speech-language therapists.

¹³ Topics Covered by the Supplemental Set for the CAHPS® Clinician & Group Survey: Adult Primary Care 1.0. Agency for Healthcare Research and Quality, Rockville, MD. December 2006. Accessed on 4/19/11 at: https://www.cahps.ahrq.gov/content/products/CG/PROD_CG_Adult_Primary_Supp_Topics.htm

Domain 1. Further, ANA recommends that care coordination experience provided by the interprofessional team in home health care setting be assessed by adding the CAHPS Home Health Care Survey to Domain 2, “Care Coordination.” ANA also recommends that CMS add to the Clinician/Group CAHPS Survey the existing supplemental questions that evaluate the care of nurse practitioners.

Comment to CMS: ANA recommends the consideration of important measures that identify the quality of care contributions provided by the interdisciplinary team and registered nurses at the individual and population level. This would focus on the two “triple aim” elements that CMS has identified as guiding its decision-making in choosing measures.

Rationale: ANA has identified some of the flaws and gaps in select quality measures that ignore the importance of interdisciplinary care teams and that undermine the goals of the “triple aim.” [Table 1, p. 19571 et seq. of the proposed rule]. These include the following:

- The measures do not reflect the mix of clinicians providing primary care or care coordination.
- The 30-day post-discharge visit requirement (Measure #9) should use language that is clinician-neutral.
- Measure #10 should include verification of medication reconciliation conducted and documented prior to hospital discharge (i.e., across discharge instruction list, prescriptions, and post-acute/long term care orders).
- The 60-day time frame for medication reconciliation post-hospitalization reflected in Measure #10 appears to be a typographical error, in that the NQF Measure #554 calls for a 30 day timeframe, to coincide with the 30-day post-discharge visit. Such a consolidation saves time and money, while protecting patient safety.
- NQF endorsed home care measures should be added. These measures focus on timely initiation of care; patient and caregiver education; preventive services; pain intervention and assessment; improvement and assessment of clinical symptoms; improvement in functional status; assessment of need for emergency care or hospitalization; and patient experience of care. ANA is mindful of the consequences of too many required measures; therefore ANA proposes that home care measures be part of the “optional” measures for which an ACO could voluntarily submit, based on the characteristics of their patient population served.

Comment to CMS: ANA recommends that, over time, specific measures should be added to the “core” set of measures to evaluate care that contributes to reducing avoidable readmissions to the inpatient setting and that promote patient engagement in care.

Rationale: It is ANA's perspective that the overall national quality of health care cannot be evaluated in the absence of data related to the structure, processes, and outcomes related to nursing care across settings. While the initial core measure set should be limited, ANA believes that other nationally recognized measures should be added or integrated into existing measures over time. Special attention should be paid to those measures that have the potential to avert or control complication of conditions that could be expensive and harmful to the patient. For example:

- *NQF-endorsed Urinary Incontinence Management in Older Adults measure and the Institute of Medicine dementia measure.* Care coordination for incontinence and dementia can avoid institutionalization of the elderly population. Registered nurses provide incontinence screening and assess the type of incontinence and implement an evidence-based incontinence management plan. Registered nurses provide dementia screening which is important to provide timely, adequate care coordination and access of community resources to keep patients safe.
- *Measures to assess community-based wound prevention related to pressure ulcers, neuropathic ulcers, and venous ulcers and wound care outcomes.* NQF-endorsed measures regarding pressure ulcers, for example, include Measure #201 in the acute care setting and #181 in the home care setting. HHS Secretary Sebelius has stated, in the context of ACO development, that chronic wound care, particularly with the diabetic population, is an area in which to improve care management and prevent unnecessary costs to the healthcare system.¹⁴ Registered nurses are skilled in providing risk assessments for wounds (i.e., pressure ulcers, neuropathic ulcers, and venous stasis ulcers) and in wound assessment and care for all wound categories/types. Registered nurses regularly categorize wounds and classify their severity (e.g., pressure ulcer stage) as part of standard nursing assessment. They are recognized experts regarding the stages of wound healing and evidence-based interventions to promote healing or to provide palliative wound care. In fact, a special category of registered nurses is certified to provide advanced wound, ostomy and continence care.¹⁵
- *Agency for Healthcare Research and Quality measures for Palliative Care/End of Life (EOL) Care.* Nurses are knowledgeable and skilled in palliative care/EOL care; in fact the hospice movement was originally started by nurses. ACOs should be required to collect data regarding the patient experience and care coordination of palliative care and EOL care. As CMS is well aware, medical expenditures in the last months of life are greater than costs during other years for Medicare beneficiaries. A 2011 study, for example, reports that the median total Medicare expenditures in the last six months of life were \$22,407.¹⁶ Avoiding unwanted interventions and emergency care for palliative care/EOL patients is an important quality indicator. The NQF is convening a Palliative Care (PC) and End of Life (EOL) Project to identify and evaluate existing PC/EOL measures.¹⁷ This would be another recommended resource for CMS's future

¹⁴ Sebelius, K. (2011). Accountable Care Organization (ACO) Proposed Regulations: ACOs will tie quality to savings (phone interview with reporters 040111). Accessed on 050411 at: <http://www.mcknights.com/feds-aco-regulations-will-tie-quality-to-savings/article/199752/>.

¹⁵ More information is available from the Wound, Ostomy and Continence Nurses Society at <http://www.wocn.org/>

¹⁶ Kelley, A.S., Ether, S.L., Morrison, M.D., Du, Q., Wegner, N.S. & Sarkisiam, C.A. (2011). Determinants of Medical Expenditures in the Last 6 Months of Life. *Annals of Internal Medicine* 154(4), 235-242.

¹⁷ National Quality Forum (NQF). (2011). Measure Prioritization Advisory Committee Report: Measure Development and Endorsement Agenda. Washington DC: NQF.

consideration of an essential quality measure regarding the provision of palliative care and end of life care.

Issue: Maximizing registered nurses' ability to assist in reducing readmissions

Comment to CMS: ANA endorses CMS's emphasis on reducing readmissions.

Rationale: ANA strongly supports the proposed outcome Measure #8 focused on the rate of readmissions to acute care facilities within 30 days. Hospital readmissions are often the result of poor care coordination and inadequate transitional care after discharge. Registered nurses play an important role in easing this transition. Nurses are often charged with providing patients and families with discharge instructions and planning, particularly instructing patients and arranging for medications, follow-up care, and special treatment regimens. Patient education and understanding are crucial to the patient's decision to adopt recommended follow-up care. RNs can also play an important role in ensuring that the patient's environment and care after discharge, whether to a home environment or health care facility, are adequate to support a full recovery. RNs are the health care professionals who are most frequently in the position to prevent the patient from acquiring or developing complications which may appear after discharge and require a readmission.

ANA acknowledges that gaps exist in measures in the areas of patient engagement and care coordination, as identified by both the National Priorities Partnership and the National Quality Strategy. As these are developed over time, ANA urges CMS to evaluate their potential to add essential information to the quality evaluation of ACOs.

Comment to CMS: Quality reporting and public accountability requirements should be augmented by making public reporting more accessible to beneficiaries with regard to variations in health literacy and numeracy. Reports should be available in the languages commonly used by ACO beneficiaries. Further, each ACO should have an ombudsperson who can discuss reported information objectively with beneficiaries seeking guidance.

Rationale: The proposed rule calls for public reporting to be in a "standardized format." ANA believes that this is not adequate guidance to assure that public information accounts for variable levels of health literacy and health numeracy. Beneficiaries must be able to understand the significance of quality data for care provided by an ACO. Reports must be translated into the languages commonly used among the beneficiaries. An ACO should also make available a person who can explain reports to people who are not literate or who can interpret for those beneficiaries whose language is not represented by common translations offered by the ACO. . When an individual wants further assistance in understanding the reported data to make informed choices, an ombudsperson should be available as a resource to offer objective guidance and to make public accountability truly meaningful.

Patient Choice of Providers

Background: CMS specifically solicits comments on the kinds of providers that should or should not be included as potential ACO participants; the potential benefits or concerns regarding inclusion or non-inclusion of certain providers; and other ways in which the

Secretary's discretion could be employed to allow the independent participation of providers not specifically mentioned in the statute.

The utilization of advanced practice registered nurses (APRNs)¹⁸ to provide primary care services cannot be called “innovative” or “new,” given that they have delivered professional health services for decades. Extensive data documents the safe, cost-effective and high quality care they provide. APRNs have the education, skills and experience to meet the needs of Medicare beneficiaries. While NPs and CNSs are cited as “ACO professionals” in the ACA, presumably recognizing their role as primary care providers, all four APRN roles – NPs, CNSs, CNMs, and CRNAs – bill Medicare Part B for primary care services for both beneficiaries who are age 65 and older, as well as those who have disabilities. Too often, though, healthcare systems are not structured to maximize the potential of this rapidly growing component of the healthcare workforce. Removing barriers to practice in federal (as well as state) laws and regulations can unleash the potential of APRNs to help achieve the “triple aim” of improving the health of the population; enhancing the patient experience of care (including quality, access, and reliability); and reducing, or at least controlling, the per capita cost of care.

Issue: The “plurality” assignment methodology described in the proposed rule unnecessarily negates primary care services provided by ACO participants other than certain primary care physicians and therefore distorts the complete assessment of who provides a beneficiary’s care .

Comment to CMS: The ACA specifies in section 1899:“(c) Assignment Of Medicare Fee-For-Service Beneficiaries To ACOs.— The Secretary shall determine an appropriate method to assign Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services provided under this title by an ACO professional described in subsection (h)(1)(A).” ANA fully understands that assignment refers only to ACO professionals who are doctors of medicine and osteopathy, and that these are further limited to certain categories of primary care practice. Further, the methodology does not include the second part of the statutory “ACO professional” definition which includes nurse practitioners, clinical nurse specialists, and physician assistants. However, ANA believes that the Secretary may have inadvertently created a situation that artificially separates some patients from their preferred primary care provider, in her statutory discretion to determine “an appropriate method to assign Medicare beneficiaries.”

ANA recommends that the proposed methodology that uses the plurality of ACO physician primary care services to make beneficiary assignment be revised. CMS can abide by the statutory requirement by basing assignment on utilization of primary care services provided by an ACO physician *without* requiring a plurality. *Any* primary care service provided by an ACO primary care physician should be enough to trigger assignment, as long as some other ACO participant has provided the plurality of primary care services to that beneficiary.

¹⁸ Advanced practice registered nurses comprise four roles: certified registered nurse anesthetist (CRNA); clinical nurse specialist (CNS); nurse practitioner (NP) and certified nurse-midwife (CNM). In the Acronyms section in the introduction to the proposed rule, CMS has defined the abbreviated terms NP and CNM but failed to include the acronyms for clinical nurse specialist, CNS. Particularly since CNSs are one of the APRN roles specified as ACO professionals, we urge CMS to include the abbreviation for CNSs in the list introducing the final rule.

Thus, the assignment methodology comports with the statutory requirement, while preserving patients' relationship with their preferred primary care provider, as long as that primary care provider is an ACO participant, including APRNs, or at least an ACO professional.

Rationale: As described in the proposed rule, a beneficiary will be assigned to an ACO if an ACO's primary care physicians provide the plurality of the beneficiary's primary care services. A Medicare beneficiary who received the plurality of his or her primary care services from an APRN would not be assigned to an ACO, even if that beneficiary's APRN was affiliated with the ACO. This scenario holds the potential to disrupt continuity of care and the patient-provider relationship. Under ANA's proposed revision, a beneficiary who received the plurality of services from an APRN participating in an ACO would be eligible for assignment based on any primary care services provided by an ACO primary care physician. At the same time, the patient would be able to continue to receive primary care services from the APRN, or other ACO participant from whom they receive a plurality of that care. ANA's recommended modification meets the ACO's goals of preserving continuity of care and patient choice, while still honoring the purpose for which the "plurality rule" was presumably based, that is, keeping beneficiaries aligned with one ACO.

Without such a change to the "plurality rule," a beneficiary who receives the plurality of primary care services from his or her APRN who is not affiliated with an ACO would simply not be assigned to an ACO. While this would still promote continuity of care and preserve the relationship between the patient and his or her primary care APRN provider, it would potentially deprive the patient (and CMS) of the hoped for benefits of that beneficiary being part of the ACO.

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 FFS beneficiaries assigned," and that the ACO will have a minimum of 5000 such beneficiaries. For systems that currently depend heavily on health care professionals other than primary care physicians to provide primary care services, the current assignment methodology may pose a problem in their ability to fulfill this eligibility requirement. Thus, an additional benefit of a change to the proposed "plurality rule" would be that it would permit smaller organizations to form ACOs by potentially increasing the number of eligible beneficiaries for which assignment may be made.

Multiple nationally recognized organizations which create quality standards for patient care have adopted clinician-neutral language to designate primary care providers. The Joint Commission's recently adopted Standards and Elements of Performance (EPs) for the Primary Care Medical Home Option (supplemental to its Ambulatory Care Accreditation Program) uses provider neutral language throughout, by referring to "primary care clinicians."¹⁹ The EPs reflects a truly patient-centered care environment, where the organization allows each patient to designate his or her primary care clinician (EPs for PC.02.01.01). Its qualification is that the "primary care clinician has the educational

¹⁹ Approved Standards and Elements of Performance (EPs) for The Joint Commission Primary Care Medical Home Option. May 19, 2011. Available at http://www.jointcommission.org/assets/1/18/Primary_Care_Home_Posting_Report_20110519.pdf

background and broad-based knowledge and experience necessary to handle most medical and other health care needs of the patients who have selected them, including resolving conflicting recommendations for care” (EP for HR.03.01.01).

Similarly, both the National Committee for Quality Assurance (NCQA) Patient-Centered Medical Home recognition program²⁰ and URAC’s Patient-Centered Health Care Homes Program²¹ have moved to clinician-neutral language to describe primary care providers. CMS should reflect the growing national consensus among influential quality organizations that place nurse practitioners and other qualified clinicians squarely within the category of primary care providers within the patient-centered medical/health home. This should be the case whether reflected in ACO primary care providers or in any other programs, demonstrations or pilots sponsored by CMS. Adopting a more narrow interpretation of primary care providers conflicts with the approach of multiple national standard-setting organizations, as well as real-world practice. Further, it rejects a significant pool of qualified primary care providers who are available to help ameliorate the country’s primary care workforce shortage.

ANA has reviewed the revised alignment algorithm that is part of the Pioneer ACO Model to be offered by the Center for Medicare and Medicaid Innovation, as described in the Request for Application accompanying the *Federal Register* notice of May 20, 2011 [Vol. 76, No. 98, pp. 29250-1]. ANA observes that the inclusion of nurse practitioners and physician assistants in the definition of primary care providers, for purposes of “beneficiary alignment,” reflects the rationale offered above for changes in the ACO proposed rule’s “plurality” calculations. We urge CMS to, at a minimum, create continuity between the two programs – the Shared Savings Program and the ACO Pioneer Model – to the full extent permitted by the ACA. ANA believes that its proposed revision of the ACO “plurality rule” achieves both these aims and urges CMS’s adoption.

Issue: The assignment of beneficiaries to an ACO under the current proposal is likely to be confusing to patients who currently receive a substantial share or all of their health care services from providers who are not affiliated with the ACO. This threatens to create a situation that undermines patient choice. Communication about assignment to an ACO has the potential to confuse the beneficiary regarding his or her rights to continue to receive services with established providers outside the ACO.

Comment to CMS: CMS has expressly noted the voluntary nature of the ACO program and its intent to avoid interfering with beneficiaries’ ability to choose their own providers. ANA recommends that the marketing materials and communication plan provisions set forth in Section 425.4 (definition of “Marketing materials and activities”) and Sections 425.5(d)(4) and (5) of the proposed rule should use inclusive language that recognizes the wide range of providers with whom beneficiaries have existing relationships. Further it should explicitly require notification from the ACO that a beneficiary has a right to (1) choose his or her

²⁰ PCMH Recognition Overview Process. NCQA. Available at <http://ncqa.org/LinkClick.aspx?fileticket=KxdSWRADg78%3d&tabid=1016&mid=5357&forcedownload=true>

²¹ URAC Patient-Centered Health Care Home [PCHCH] Programs. Available at http://www.urac.org/healthcare/pchch_faq.aspx

primary care and other providers and (2) continue his or her relationship with that primary care or other provider, regardless of whether the provider is an ACO provider. The notice should require the ACO to emphasize the voluntary nature of the beneficiary's participation in the ACO and that sharing CMS claims data is also voluntary.

Rationale: Under the proposed rule, beneficiaries who receive *all* of their primary care from APRNs will not be assigned to an ACO, which will promote continuity of the patient-provider relationship for those beneficiaries.

The problem lies with those APRN primary care providers who are not ACO participants but whose patients are assigned to an ACO. Beneficiaries who rely on these APRNs for much of their primary care, but who have also seen ACO MDs/DOs for the plurality of their primary care *service* during the defining assignment period, will be assigned to an ACO. Nothing in the ACA indicates that Congress intended for beneficiaries who rely largely upon the primary care services of APRNs to be automatically excluded from ACOs.

Under the proposed rule, some beneficiaries who receive the plurality of their primary care work Relative Value Units (RVUs) from APRNs not participating in an ACO may nevertheless be assigned to an ACO. This is due to the existing, prejudicial Medicare payment rules for APRNs. The result can be the disruption of the continuity of the patient-APRN relationship for those beneficiaries.

The problem here lies in the mandatory discount applied to approved charges from NPs and CNSs. Their approved charges for primary care services are set at 85% of the Medicare Physician Fee Schedule amount. This discounting of APRN primary care services can tip the balance as to whether the beneficiary is assigned to an ACO where he or she may have received primary care services from the ACO's primary care physicians but in lesser amounts than provided by the advanced practice registered nurse.²²

Our preferred remedy in this case would be to follow the recommendations of the Chair of the IOM Study on the Future of Nursing and pay according to the value of the service rather than the specialty of the provider. Failing that, ACO assignment should be based on the plurality of the work RVUs associated with primary care services.

Given both the communications from CMS, as well as marketing materials from the ACO, beneficiaries may not understand that participation in the ACO is voluntary, despite the requirement that this qualification be included in beneficiary communications. Beneficiaries could easily interpret assignment as a direction from Medicare that they can no longer seek care from their APRN outside the ACO.

²² For example, a beneficiary in Silver Spring, Maryland might have a health care home with an NP who assesses that patient's chronic care status once per quarter during a level 3 follow-up office visit. Assume the beneficiary also received two level 3 established patient office visit with an FP for a different complaint. Further assume that the patient had subsequently been referred to an internist for another evaluation resulting in a claim for a level 3 initial patient office visit. The NP would have provided a total of 4.08 work RVUs in primary care. If the two MDs are in the same ACO, the ACO's primary care physicians would have provided a total of 3.53 work RVUs. The plurality of primary care RVUs was provided by the NP. Based on the approved charges for those services, the physicians' total would be \$272.70 while the NP's total would be \$265.47, so the patient could be assigned to the ACO rather than the patient's usual source of care.

CMS states that “the Shared Savings Program lays the foundation for a beneficiary-centered delivery system that should create a strong relationship between beneficiaries and care providers...” and intends to develop a communication plan to further that goal. To support this objective, both the communication plan and any marketing materials should highlight clear and unambiguous information to beneficiaries that their right to seek care of their choice from the provider of their choice is not dependent on their assignment to an ACO. Similarly, these materials should not suggest that the beneficiary will somehow receive inferior care if he or she seeks care outside the ACO.

Issue: In multiple instances the proposed rule unnecessarily refers only to physicians, e.g. the assignment methodology, physician-directed quality programs and the post-discharge physician visit. This perpetuates a system overly dependent on physicians when the burgeoning growth of the Medicare population demands innovative models of care that utilize a wide array of health care professionals. This physician-centric perspective, reflected throughout the proposed rule, runs counter to the goal of building patient-centered interdisciplinary teams.

Comment to CMS: ANA recommends that the proposed rules be more inclusive of NPs and CNSs in clinical, management and leadership aspects of the ACO such as assignment, quality assurance and quality measures such as the 30 day post-discharge visit. The ACO will need to promote the use of NPs and CNSs as well as other health care professionals to meet the needs of beneficiaries. If the ACO rule is to establish the framework for many other future versions of the Shared Saving Program – demonstration projects, etc. – then in order for it to be effective and respectful of beneficiaries’ individual needs and choices, it must be non-discriminatory and non-preferential toward different types of providers

Rationale: A truly reformed healthcare system must acknowledge an evolved healthcare workforce if we are to meet the goal of the “triple aim.” There are approximately 250,000 APRNs and 900,000 physicians (MDs/DOs) in the US. In 2009, 92,472 APRNs participated directly in Medicare Part B. Many serve Medicare (and Medicaid) patients who often struggle to access care. Many physicians no longer accept Medicare patients because of low reimbursement. The Joint Commission reported that poor communication was the number one cause of sentinel events. Building patient-centered, team-based care requires “a combination of frequent, substantial communication; a deep base or shared goals and knowledge; and mutual respect.... In other words, teamwork requires more than just having other staff more effectively support physicians. It involves building and sharing a collective identity as a true team.”²³ This relational and communications coordination among healthcare professionals improves patient care, safety and satisfaction.

Issue: Innovative models of community based care, in addition to Federally Qualified Health Centers (FOHCs) and Rural Health Centers (RHCs), are not among those delivery systems for which the ACO can receive incentives for including.

Comment to CMS: ANA recommends that the final rule facilitate the inclusion of innovative models of care, recognized and supported in other provisions of the ACA, which

²³ Chesluk, B.J., Holmboe, E.S. (2010) How Teams Work – Or Don’t – in Primary care: A Field study on Internal Medicine Practices.” Health Affairs 29(5):p. 875.

are led by providers other than physicians. ANA recommends that the incentives relevant to FQHCs and RHCs also be applied to nurse managed health centers (NMHC), and school-based health centers (SBHC).

Rationale: CMS has proposed that an ACO can receive an increase in its shared savings rate for including a strong FQHC and/or RHC presence. The rationale for providing incentives to include a strong FQHC and/or RHC presence within the structure of an ACO apply to NMHCs and SBHCs as well. Like FQHCs and RHCs, these are innovative models of community-based care that focus on outreach, disease prevention and patient education. They provide high quality, cost effective care to underserved populations.

PAYMENT REFORM AND GOALS OF THE ACO

Issue: Assuring adequate funding and staffing for ACO's care coordination function and care coordinators

Comment to CMS: ANA recommends that CMS develop ACO program applications that require organizations to include a detailed plan for maintaining and enhancing care coordination activities across all settings in which assigned beneficiaries receive Medicare covered services. In addition, the application must document the qualifications of proposed care coordination staff (or job titles), and the care coordination experience required prior to hiring, placing, or securing the services of those personnel. Further, the applications must clearly document the care coordination funding levels over the course of the three year contract, and monitoring steps that will be implemented to assure adequate staffing by experienced personnel for the duration of the project.

Rationale: The twin objectives for the ACO program are reductions in the cost of care for Medicare patients and improvement in the quality of care delivered to those patients. The novelty in this approach is that there are direct financial incentives to encourage the accomplishment of both goals. The linchpin to accomplishing those goals, however, is care coordination. For this reason, it is important that organizations that apply for ACO status must be prepared to properly support the care coordination function and the on-the-ground employees/contractors/partners that will be responsible for care coordination.

Care coordination is such an important aspect for ACO success that regulatory parameters for its implementation should not be sacrificed in the name of providing "flexibility" to the ACO. Some guidance should be available to set minimum standards, reflecting evidence-based practice. In developing a quality assurance plan for ACO beneficiaries, a great deal of attention will be paid to clinical services and the plans for organizing multi-disciplinary health care professional teams. In all likelihood, most if not all such professionals will understand the need for care coordination and the functions that are entailed. But we know today that much care is uncoordinated despite the understanding and good intentions of the clinicians involved. *The vital lesson to be applied to the development of the final rule is that care coordination must be achieved by design.*

Because of the importance of care coordination from the outset, it is recommended that applicant organizations be required to document that aspect of their proposal with specific names, dates, and schedules to assure its proper function. With the experience gained from both the Physician Group Practice (PGP) and Medicare Coordinated Care Demonstrations, CMS should establish specific guidelines and budget parameters that must be met by ACO applicants before additional consideration of any proposal. ACOs should not be allowed to fail because they did not plan carefully enough to support their care coordinators and the care coordination function.

Issue: Using savings to benefit patient care

Comment to CMS: ANA supports CMS's requirement that an ACO should describe in detail its plan to meet the "triple aim"

Rationale: ANA applauds proposed section 425.5(d)(11)(iii), requiring that an ACO describe in its application a plan to "achieve the general aims of better care for individuals, better health for populations, and lower growth in expenditures." ANA views the integration of these provisions to meet the program's goal to "encourage[s] investment in infrastructure and redesigned care processes for high quality and efficient services" [Section 425.2(a); p. 19640]. It is understandable that, to attract applicant ACOs, shared savings must be sufficient to, at a minimum, help defray administrative costs and revenues lost as a result of reducing utilization. Balancing this is the fundamental purpose of an ACO to improve and support patient care. As the health care profession which is more involved in direct patient care than any other, registered nurses particularly see the need to tie savings under the ACO model back to benefitting direct patient care.

Conclusion

ANA strongly supports the move to a patient-centered healthcare delivery system based on interprofessional collaboration and a focus on improving the quality and coordination of care. We are disappointed that the proposed regulation implementing the ACO shared savings program does not recognize the essential role registered nurses and APRNs play in achieving these goals. The proposed rule does not create a structure for true interprofessional teamwork, where each health care professional is acknowledged as delivering a unique set of skills that complement those of other providers in the team.

A cornerstone competency of nursing is care coordination, an element at the core of the ACO's purpose to improve care quality and control costs. In addition, registered nurses and APRNs are acknowledged leaders in developing transitional care models, chronic disease management programs and other initiatives that help keep costs down while improving patients' quality of care. These very programs are among those that will help to reduce adverse drug events, emergency department utilization, and hospital readmissions, among the most expensive potentially avoidable expenditures in the Medicare budget. Quite simply, a de-emphasis on nursing will dramatically reduce both an ACO's chance of success and CMS's chance to save money.

In its recent report, *The Future of Nursing: Leading Change, Advancing Health*, the Institute of Medicine's independent committee of national experts in healthcare concluded that nurses are

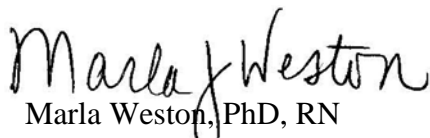
poised to help bridge the gap between coverage and access, to coordinate increasingly complex care for a wide range of patients, to fulfill their potential as primary care providers to the full extent of their education and training, and to enable the full economic value of their contributions across practice settings to be realized. In addition, a promising field of evidence links nursing care to high quality care for patients, including protecting their safety. Nurses are crucial in preventing medication errors, reducing rates of infection, and even facilitating patients' transition from hospital to home.²⁴

The Joint Commission, the National Quality Forum, and countless other nationally significant healthcare organizations have acknowledged registered nurses as leaders in high quality care and patient safety, and APRNs as qualified primary care providers. If CMS wants Accountable Care Organizations to be the face of the future of healthcare, it must recognize nursing's central role in the success of ACOs.

ANA appreciates the opportunity to comment on CMS's proposed rule. ANA and the nursing community stand ready to provide whatever assistance that CMS may need in order to capitalize on nursing's unique contributions to patient care and the interprofessional care team. To do so will help assure that ACOs are truly accountable to the patient, to the provider, and to the taxpayers who support the Medicare system.

If we can be of further assistance, or if you have any questions or comments, please feel free to contact Cynthia Haney, Esq., Senior Policy Fellow, Department of Nursing Practice and Policy, at Cynthia.haney@ana.org, or 301-628-5131.

Sincerely,

A handwritten signature in black ink that reads "Marla Weston". The signature is fluid and cursive, with the first name "Marla" and last name "Weston" clearly distinguishable.

Marla Weston, PhD, RN
Chief Executive Officer
American Nurses Association

cc: Karen Daley, PhD, MPH, RN, FAAN
President, American Nurses Association

²⁴ Institute of Medicine (IOM), p. S-3.