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May 31, 2011

Donald M. Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 21244-1850

Re: **Medicaid Program; Medicare Shared Savings Program: Accountable Care Organizations
CMS -1345-P**

Dear Dr. Berwick:

National Patient Advocate Foundation (NPAF) would like to thank you for the opportunity to comment on the Medicare Shared Savings Program proposed rule which is designed to promote accountability for the patient population, coordinate items provided and services rendered to patients under Parts A and B and encourage investment in infrastructure for high quality and efficient patient service delivery. The rule introduces accountable care organizations (ACOs), a new category of Medicare provider designed to provide high-quality coordinated care to patients. The rule has the potential to positively transform the delivery of quality healthcare services to Medicare fee-for-service patients. The balance of this letter provides NPAF's comments on the Medicare Shared Savings Program structure in general and ACOs eligible to participate in the program proposed in the rule and their impact on patients.

NPAF is a non-profit organization dedicated to improving patient access to healthcare services through both federal and state policy reform. Its mission is to be the voice for patients who have sought care after a diagnosis of a chronic, debilitating or life-threatening illness. While other commenters may find responding to a patient-centric rule to represent a new paradigm, NPAF has a fifteen year history of serving as the trusted patient voice. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive direct, sustained case management services from our companion organization, Patient Advocate Foundation (PAF). In 2010, PAF resolved 82,963 cases nationally and provided information to almost 4 million online contacts. PAF's Patient Data Analysis Report, which will be described in greater detail later, provides detailed analyses of these cases.

Patient Centeredness Criteria

NPAF applauds the Centers for Medicare and Medicaid Services (CMS) for its focus on assuring the true beneficiary of the rule is the patient. A few examples of this focus include the ACO patient-centeredness criteria, patient governance participation language and patient experience as an important proposed ACO quality standard measure. The elevation of patient-centered

criteria as essential is also evident. NPAF commends the decision to have ACO eligibility criteria include the applicant's ability to demonstrate to the agency that it meets patient-centeredness criteria, such as the use of patient caregiver assessments or the use of individualized care plans. The proposed rule is generally consistent with the recommendations offered by the Commonwealth Fund to ensure the success of ACOs.¹ NPAF's recognition of the potential ACOs have to positively transform the delivery of quality healthcare services to Medicare fee-for-service patients leads it to suggest CMS adopt the Commonwealth Fund's recommendation that CMS develop and test different approaches to providing positive incentives to encourage patients to designate an ACO as their principal source of care.

While NPAF is in strong support of the ACO concept because of the potential it represents to positively transform health care delivery for Medicare fee-for-service patients, we are aware of the many concerns raised by healthcare providers regarding the complexity and economics of the proposed rule. NPAF advises CMS to expand upon the aforementioned recommendation by the Commonwealth Fund to develop and test different approaches to encourage patients to designate an ACO by also encouraging *providers* to participate in the Shared Savings Program. NPAF was concerned to read that the American Medical Group Association finds the rule to be, "overly prescriptive, operationally burdensome," and that the incentives are "too difficult to achieve to make this voluntary program attractive."² NPAF's concerns grew when we learned all ten multi-specialty groups participating in the Physician Group Practice Demonstration Program had "serious reservations about the economics and the complexity" of the program as described in the proposed rule. A greater number of providers that participate in the program will result in a greater number of opportunities for patients to benefit from the coordinated efficiencies of an ACO model. While NPAF encourages CMS to make the Shared Savings Program more attractive to providers, we caution that the proposed rule should not be amended in a manner that makes the program more attractive to providers yet erodes patient clinical or financial benefits. For example, we understand some health stakeholders have expressed concern regarding the ability of patients to opt out of data-sharing. While NPAF understands CMS must balance patient right of choice versus its need for data, we advise that patient choice should be prioritized so that this rule is truly patient-centric.

Shared Savings Program and Patients

Perhaps the greatest benefit to patients will be that the Shared Savings Program constitutes a Medicare delivery system reform as opposed to a mere payment system reform. Past Medicare payment system reforms have been myopic in their approach to restrain costs without considering patient consequences. These reforms evidenced an approach that was finance-centric and not patient-centric. For example, diagnosis-related groups (DRGs) were designed to reduce the rate of hospital Medicare payments as well as to provide incentives for hospitals to produce high-quality patient care at the lowest possible cost.³ However, some DRGs became more profitable than others as evidenced by MedPAC's report that showed patients requiring heart by-pass procedures were more profitable to hospitals than patients admitted for pneumonia.⁴ These differences may have contributed to changes in care delivery.⁵ Not all of those changes were positive ones for patients. When comparing the outcomes of care before and after DRG implementation, a study revealed that although on average outcomes had not

¹ M.A. Zezza and S. Guterman, Perspectives on Health Reform – Achieving Accountable Care: Are We on the Right Path? The Commonwealth Fund, April 2011.

² American Medical Group Association, "Medicare Shared Savings Program: Accountable Care Organizations, May 2011

³ See Steven Sheingold "Unintended Results of Medicare's National Prospective Payment System," *Health Affairs*, 5, no.4 (1986):5-21

⁴ Julian Pettingill, Medicare Payment Advisory Commission, presentation to the commission, 29 October 2004.

⁵ Paul Ginsburg "When the Price Isn't Right: How Inadvertent Payment Incentives Drive Medical Care," *Health Affairs*, no. 9 (2005):

worsened, clinical instability of patients at discharge increased after DRG implementation. This meant patients were being discharged “quicker and sicker”. NPAF cautions that care should be taken to assure the ACO delivery system reform benefits do not become overshadowed by the profit sharing payment potential as such a transformation may occur at the peril of patients.

NPAF has considered the rule’s effect on patients, particularly as it relates to beneficiary assignment to ACOs. On the one hand, NPAF understands and appreciates the benefits of retrospective assignment. It allows for ACO evaluation on the quality and cost of care furnished to those beneficiaries who actually chose to receive care from ACO participants during the course of each performance year. It also encourages the ACO to redesign its care processes for all Medicare FFS beneficiaries, not just for the subset of beneficiaries upon whom the ACO is being evaluated. CMS must assiduously monitor of any attempt by ACOs to identify and avoid at-risk beneficiaries that appear on the list so that the costs of these beneficiaries do not appear in the calculation of the ACO’s actual expenditures during a performance year.

While there are benefits of retrospective assignment, CMS must assure these benefits do not preclude the ability of assigned beneficiaries to prospectively select their provider. As will be explained later in the section on beneficiary assignment, beneficiaries with chronic, debilitating, or life-threatening diseases should be able to receive their services, including primary care services, from specialty providers. For example, patients suffering from cancer likely receive the majority of their health care services, including primary care services, from specialists.

A final over-arching issue regarding the shared savings program and patients concerns patient access to specialty care. Specialty care is care that addresses complex illnesses, involves multiple points of care, and requires complicated case management. Patients assigned to ACOs should have access to specialty care as needed. The resultant care provided by these specialists, such as reliance on medical imaging and supportive care practices should be seamless within a coordinated care system and not treated as ancillary or adjunct. True coordination of care must include specialists in the clinical patient care analyses and decisions.

Entity Participation. The shared savings program rewards providers who can demonstrate their collaboration results in more accountable, effective and efficient care with a share of the savings they achieve. Unlike earlier forms of Medicare payment reform, the shared savings program incorporates patient outcomes directly into the provider payment model. There is a correlation between positive patient outcomes and greater provider payment which will provide a strong incentive for providers to assure positive patient outcomes. This promising model offers great benefit to the patient and is one that should be available to a large number of providers so that a greater number of patients can enjoy this important benefit. NPAF agrees with the CMS approach in exercising its statutory authority to define ACO participation in the shared savings program by expanding, rather than narrowing the types of entities that can participate in the shared savings program.

The expansion of types of entities that can participate should also include a rule that is flexible enough to allow for and reward existing high-quality providers. The shared savings program is premised upon sharing savings that result from improvement in the delivery of coordinated care. Assume eligible providers were to be categorized into a) walkers-those that are at the lower end of the spectrum in their ability to deliver coordinated care; b) joggers- those providers that are in the mid-range of the spectrum in their ability to deliver coordinated care; and c) the most desirable providers as marathoners- providers that have been at the forefront in providing documented quality patient care at reasonable costs. The shared savings program must be as attractive to marathoners as it is to walkers. The current shared savings program structure will reward the walkers who become marathoners significantly greater than it will reward those marathoners who are in the forefront of the marathon class and remain there. Many of the marathoners may likely be in the marathon category because they have effectively utilized the advances in medical treatment and technology, such as electronic assist tools. NPAF applauds the recent CMS announcement of the Pioneer ACO program

which will allow those providers at the head of the pack to accelerate their participation in the shared savings program in coordination with private insurers.

To assure a positive “take-up” rate of the Shared Savings Program by high-performing providers, CMS may want to consider a bonus payment for existing high-performing ACOs. The participation of high-performing ACOs in the shared savings program will directly benefit Medicare fee-for-service patients. The new addition to the rule which allows for an advance payment model for providers who lack access to capital is also applauded. This approach would likely benefit the walkers.

It is certain all providers that participate in the Shared Savings Program will change their treatment patterns as the result of coordination of care. Failure to reflect these changing treatment patterns in the baseline could discourage use of the new technology when clinically appropriate. There is precedent for treating new technology differently in its first years, specifically to ensure that beneficiaries have access to appropriate care as treatments change. CMS provides transitional pass-through payments to hospitals via the Medicare outpatient prospective payment system (OPPS) for drugs, biologicals, or devices. NPAF recommends that CMS include a similar transitional pass-through payment for Shared Savings Program participants as use of new technological advances benefits patients. In order to ensure beneficiaries’ continued access to these new treatments in the ACO context, CMS should remove any payments for drugs and devices that receive transitional pass through payments that are associated with ACO-eligible beneficiaries from both the benchmark and spending calculations during the time that they receive transitional pass through payments.

Beneficiary Assignment. NPAF also welcomes and concurs with CMS’ focus on at-risk populations such as the frail elderly. Those providers which have historically provided care to a significant proportion of at-risk populations should be included in the definition of ACOs eligible to participate in the shared savings program as the benefit of their inclusion inures to the at-risk populations they serve. While NPAF applauds the inclusion of Federally Qualified Health Centers (FQHCs) and rural health centers (RHCs) as within the range of eligible providers permitted to participate in ACOs, it requests CMS reconsider its prohibition of the assignment of Medicare patients to them for shared savings program participation. The Health Resources and Services Administration Uniform Data System shows that from 1996 – 2009 the FQHC Medicare patient population grew by 124%⁶. Rural Health Clinics exist to improve access to primary care in underserved rural areas as rural populations are also at-risk. According to the Kaiser Family Foundation, in 2010, 21 percent of Medicare beneficiaries lived in rural counties.⁷ They are more likely to be fee-for-service beneficiaries as Medicare Advantage market penetration is lower in rural areas.⁸ Precluding this population from ACO assignment will result in the exclusion of the poorest beneficiaries with the most severe health outcomes. Their absence will skew overall ACO program outcome data and compromise its validity for underserved communities. Most important, this population is most in need of having its care coordinated as FQHCs and RHCs do not provide tertiary services.

Beneficiary assignment to ACOs as proposed in the rule could exempt another vulnerable population—those with chronic, life-threatening or debilitating diseases. Section 3022 of the *Affordable Care Act*⁹ requires beneficiary assignment to an ACO to be based on the beneficiary’s utilization of primary care services. NPAF is concerned that CMS’ broad interpretation of this section of the law prevents this vulnerable population from participating in ACOs. The statute allows HHS to assign Medicare fee-for-service beneficiaries to an ACO based primary care services use provided by an ACO professional. ACO professionals are defined in statute as any physician or practitioner allowed to bill under the physician

⁶ *Medicare’s Accountable Care Organization Regulations: How Will Medicare Beneficiaries who Reside in Medically Underserved Communities Fare?* Sara Rosenbaum and Peter Shin April 2011. Policy Research Brief #23, Web. 25 April 2011

⁷ Henry J. Kaiser Family Foundation, “*Medicare Chartbook 2010 Percent of Medicare Beneficiaries Residing in Rural Counties, 2010, by State, May 2010*”

⁸ Henry J. Kaiser Family Foundation, “*Medicare Advantage in 2008*” June 2008

⁹ Pub.L. 111-148

fee schedule. This broad definition of ACO professional, as well as statutory language directing assignment to be based on the type of services rendered and not on the type of provider expands patient assignment to ACO potential.

The resultant proposed rule appears to exceed statutory authority by limiting the physician specialties which will trigger beneficiary assignment to general practice, family practice, internal medicine or geriatric medicine. This limitation narrows the Medicare population eligible for ACO assignment significantly. Fee-for-service Medicare beneficiaries who receive primary care services from specialists will not be assigned to ACOs. The physician specialty limitation overlooks an important fact touted by CMS in support of the ACO program- more than half of Medicare beneficiaries suffer from five or more chronic conditions, such as diabetes, arthritis, hypertension, and kidney disease. They are more likely to receive primary care services from specialists. The Patient Data Analysis report approaches this finding. In 2010, 17.86% of patients contacting PAF for assistance reported having two or more health conditions.¹⁰

The limitation of physician specialties triggering beneficiary assignment also harms the very patients most in need of care coordination from both a clinical, as well as a financial perspective. A Congressional Budget Office report found that Medicare beneficiaries who spent the most for their care were more likely to suffer from chronic conditions, such as coronary artery disease and diabetes.¹¹ The need for patient care coordination for successful treatment of these diseases is imperative. Thus, preventing patients who receive their primary care services from specialists (and are therefore most in need of coordination of services), from ACO participation frustrates the very goal of the Shared Savings Program- to encourage providers to coordinate patient care by rewarding those providers who can demonstrate their collaboration results in more accountable, effective and efficient care by rewarding them with a share of the savings they achieve.

A final note regarding beneficiary assignment concerns another important at-risk population that is not appropriately highlighted in the rule- dual eligibles. These are people who receive benefits from both Medicaid and Medicare and are among the most chronically ill and costly segments of both programs. PAF's Patient Data Analysis Report, which will be described in greater detail later, reveals in 2010, almost 11% percent of the people requesting assistance from PAF were dual eligibles. Fifteen percent of Medicaid enrollees are dual eligibles; however, these enrollees represented 40 percent of Medicaid spending in 2007.¹² Sixty percent of dual eligibles have multiple chronic conditions.¹³ This population has suffered from unintended negative consequences of national health policy reform, such as the implementation of Medicare Part D which not only required dual eligibles to participate in the program, but removed the protections found in Medicaid law and made them susceptible to privately-administered prescription drug plans. CMS should assure the newly-created Federal Coordinated Health Care Office reviews the resultant ACO policies to protect this population from unforeseen outcomes, and unintended consequences. NPAF encourages CMS to develop a pilot program that specifically monitors the care dual-eligibles receive under Medicare Parts A, B, and D to determine whether there are shifts in their care to achieve cost-savings. The cost to the patients in participating in the ACO must also be carefully monitored.

No matter the criterion CMS ultimately decides to use for ACO beneficiary assignment, it is important that the beneficiary is notified of the assignment, particularly if the assignment is retrospective. No rule can be patient-centric if it does not allow for an informed patient voice. *NPAF does not advocate for patient notification because it is concerned about retrospective ACO assignments in general but rather because its fifteen year history as a trusted patient advocate enables it to understand that*

¹⁰ Patient Advocate Foundation, "Patient Data Analysis Report 2010" May 2011

¹¹ Congressional Budget Office, *High Cost Medicare Beneficiaries*, (May 2005).

¹² Among Dual Eligibles: Implications for Patterns of Medicaid and Medicare Service Use and Spending. Kaiser Commission on Medicaid and the Uninsured. Kaiser Family Foundation, July 2010.

¹³ Report to the Congress: Aligning Incentives in Medicare. MedPAC, June 2010 Chronic Disease and Co-Morbidity

patient trust is the bedrock of quality patient care and such trust is eroded if patients are not provided an opportunity to become as informed of their care as they choose.

ACO Eligibility Requirements to Participate in Shared Savings Program

Section 1899(b)(2) of the Act identifies a number of requirements which ACOs must satisfy in order to be eligible to participate in the Shared Savings Program. Subsection G requires ACOs to “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.” NPAF applauds CMS’ decision to allow ACOs to satisfy eligibility requirements under this subsection by providing documentation in its application plans to: (1) promote evidence-based medicine; (2) promote beneficiary engagement; (3) report internally on quality and cost metrics; and (4) coordinate care. It encourages CMS to consider the expertise of the nonprofit community in determining whether an entity has sufficiently met these requirements, particularly those addressing the promotion of beneficiary engagement and coordination of care. The processes to promote patient engagement identified in the proposed rule represent a solid foundation. The use of decision assist support tools and shared decision making methods with which the patient can assess the merits of various treatment options in the context of his or her values and convictions is important, and it correlates positively with patient compliance to medical advice. CMS should also identify minimal patient engagement compliance criteria which all ACOs must comply. For example, all materials should have to be written at a sixth grade reading level. Those who draft these materials must also be careful about the use of complex sentence structure, the use of unnecessary medical terms and when certain medical terms are needed, including definitions and explanations. Concrete language must be in place to ensure easy navigation, even if it means giving explicit instructions where a specific treatment is being discussed without having to refer to another page.

ACO application information regarding proposed processes to promote coordination of care should be reviewed with diligence as it represents the foundation of this payment paradigm shift. CMS aptly defined coordination of care as strategies to promote, improve, and assess integration and consistency of care across primary care physicians, specialists, and acute and post-acute providers and suppliers, including methods to manage care throughout an episode of care and during its transitions, such as discharge from a hospital or transfer of care from a primary care physician to a specialist. A range of possible strategies are identified which include capability to use predictive modeling, promotion of telehealth and utilization of case managers in primary care offices. NPAF encourages CMS to consider recommending to ACOs that they contract with nonprofit groups that have experienced case managers to provide this important service. The retrospective assignment of fee-for-service Medicare beneficiaries will likely necessitate a high level of sophisticated case management not likely to be attained by merely hiring a case manager. Nonprofits that have case managers who specialize in certain areas will benefit ACO assignees best.

While much attention in the ACO rule is focused on the shared savings program, a more important part is the section on patient-centeredness criteria. Savings can only be shared if they exist in the first place, and they are not likely to exist without assigned Medicare beneficiaries adherence to medical advice. Beneficiary compliance with and adherence to recommended treatment over time will result in improved health at less cost. CMS’ definition of patient-centered care as “care that incorporates the values (to the extent the informed, individual patient desires it) of transparency, individualization, recognition, respect, dignity, and choice in all matters, without exception, related to one’s person, circumstances, and relationships in health care” is both thorough and accurate. As noted earlier, NPAF is uniquely qualified to make this assessment as it is not a newcomer to the issue of patient focused care, but rather has been a champion and voice for patients for over 15 years.

There is another important reason why NPAF can competently comment on the sufficiency of CMS’ identification of processes and actions necessary to ensure the patient-centered orientation as specified in the Act. Since its inception, NPAF has availed itself of the patient data collected by its

companion organization, the Patient Advocate Foundation (PAF). PAF produces an annual patient data analysis report (PDAR) which provides a current overview of patient difficulties in accessing healthcare in America. A copy of that report is attached to this letter. The PDAR reflects the extensive documentation recorded by PAF case managers as they resolve cases and input data on 260 unique data fields. Thus, the following NPAF comments regarding each of the eight proposed patient-centered criteria are both evidence-based as well as data-driven.

- **ACOs must have a beneficiary experience of care survey in place and a description in the ACO application how the ACO will use the results to improve care over time.** This criterion is an important one as it requires the ACO to respond to the collective patient voice. NPAF agrees that ACOs should be directed to implement the Agency for Healthcare Research and Quality's Clinician and Group Consumer Assessment of Healthcare Providers and Systems survey. Its valid and reliable outcomes allows for extrapolation across entities thereby promoting robust data collection and extrapolation. For this reason, NPAF discourages the suggestion that ACOs be allowed to employ survey tools of their own choosing. As noted in the rule, this approach would impede CMS' ability to compare beneficiary experience across ACOs and would therefore soften the beneficiary voice. For reasons explained in the third bullet, NPAF recommends ACOs utilize the survey instrument AHRQ utilizes in its National Healthcare Disparities Reports when surveying minority populations.
- **ACOs must have a Medicare beneficiary on the governing board.** ACO board representation by Medicare beneficiaries is important if there is to be a true partnership between them and the ACO. However, the partnership should not be one characterized whereby the beneficiary is merely a limited partner. Because there may not be a level playing field in terms of board members whose concerns are fiduciary and a single board member whose interests are to represent the beneficiaries, NPAF proposes that, to the extent allowed by state law, the number of Medicare beneficiaries on the board represent a plurality, or at least more than one member. This approach would allow for adequate beneficiary representation and assure that beneficiary needs are not overshadowed by the desire to elevate savings. The ACO may also choose to select a nonprofit with considerable patient advocacy experience to serve on its board as the patient beneficiary representative. NPAF also recommends specialists be placed on the ACO governing board to assure true coordination of patient care across the ACO.
- **ACOs are required to have a process for evaluating the health needs of the ACO's population, including consideration of diversity in their patient populations, and a plan to address the needs of their population.** NPAF echoes the importance of considering population health, particularly as it relates to the diverse needs of discrete segments of the population. This criterion provides an opportunity to begin to address an issue that has plagued the country's health care delivery system for far too long. While a fragmented health system has jeopardized quality of care for all Americans, challenges with the current health care delivery system has disproportionately affected minority populations. For example, minority groups experience rates of preventable hospitalizations that approach double the rate of non-Hispanic whites.¹⁴ The challenges that these health disparities evidence result in outcomes that affect all in America. The combined costs of health inequalities and premature death in the United States totaled \$1.24 trillion between 2003 and 2006.¹⁵ The Department of Health and Human Services has recently released the HHS Action Plan to Reduce Racial and Ethnic Health Disparities. Strategy I.C. entitled, "Reduce Disparities in the Quality of Healthcare" is closely aligned with the intent of this patient-centered requirement. NPAF encourages CMS to integrate the recommendations outlined in the report and to capitalize on the validity and

¹⁴ Centers for Disease Control and Prevention (CDC). CDC Health Disparities and Inequalities Report – United States, 2011 MMWR 2011; 60(Supplement); 1-114.

¹⁵ Joint Center for Political and Economic Studies. Patient Protection and Affordable Care Act of 2010: Advancing Health Equity for Racially and Ethnically Diverse Populations. Washington, DC; 2010.

reliability of the survey instrument utilized by AHRQ in its National Healthcare Disparities Reports when surveying minority beneficiaries. This most recent version of this report revealed that core indicators of quality of care in preventive care, acute treatment and chronic disease management received by ethnic and minority populations is not optimal.¹⁶ When considering challenges of special populations, the challenges faced by rural patients should likewise be considered. According to the Health Resources and Services Administration, rural residents experience greater rates of chronic disease than any other segment of the US population.¹⁷ The high chronicity of disease for this population translates into a great need for coordination of care.

- **ACOs must evidence systems in place to identify high-risk individuals and processes to develop individualized care plans for targeted patient populations, including integrating community resources to address individual needs.** The rule's language requiring ACOs to develop, update, and as appropriate, share the beneficiary care plan with others involved in the beneficiary's care, and providing it in a format that is actionable by the beneficiary is one that NPAF strongly supports. NPAF concurs that the individualized care plan should include identification of community and other resources to support the beneficiary in following the plan as integration of community resources into the ACO is an important part of patient centeredness. However, the definition of community should not be limited to geography. The Internet, electronic medical records and other electronic media have changed the healthcare community as we know it. For example, PAF provides access to prescriptive drugs for people throughout the country in its multiple prescription drug assistance programs. PAF services include case management services, MedCare Line services- which provides patient education on specific diseases and emerging therapies, co-pay relief programs- which deliver direct financial support for patients as well as a free prescription drug program. *The many PAF case managers who are not geographically proximate to the patients they serve would certainly be considered a part of the patient's health community. PAF, or other prominent national nonprofits should not be denied an opportunity to serve as a community patient advocate in the development or implementation of individualized patient care plans. A definition of the community in terms of geography is also at odds with the rule's patient-centered criterion regarding the promotion of electronic records, home monitoring, telemedicine and other electronic media described in the next bullet.*

- **ACOs must have a mechanism in place for the coordination of care for Medicare beneficiaries which must include a process to electronically exchange summary of care information during care transitions.** NPAF concurs with CMS' approach regarding ACO ability to request beneficiary identifiable claims data for beneficiaries. ACOs may only request such data from beneficiaries who have (1) visited a primary care participating provider during the performance year, and (2) have not chosen to opt-out of claims data sharing. NPAF concurs with an opt-out approach for the reason provided in the rule – it is used successfully in most systems of electronic exchange of information because it is significantly less burdensome on consumers and providers yet still provides an opportunity for caregivers to engage with patients to promote trust and permits patients to exercise control over their data. Another important reason is that it allows comparison of aggregate health outcomes of non-beneficiary identifiable claims data from beneficiaries who have opted out of claims data sharing to those of beneficiaries who have not chosen to opt out.

A beneficiary who chooses to opt-out is only opting out of the data sharing portion of the program. NPAF is pleased to read the decision of beneficiaries to opt-out in no way effects use

¹⁶ Agency for Healthcare Research and Quality (AHRQ). National Healthcare Disparities Report, 2008. Rockville, MD; 2009.

¹⁷ Office of Rural Health Policy, Retrieved May 5, 2011 from <http://www.hrsa.gov/about/organization/bureaus/orhp/>

of the beneficiaries' data or assignment to the ACO for purposes of determining such calculations as ACO benchmarks, per capita costs, quality performance, or performance year per capita expenditures. NPAF recommends CMS vigilantly monitor whether ACOs continue to request data on beneficiaries who have opted out of having their data shared and take appropriate actions against any ACO that is found to violate this requirement.

The mechanisms adopted by ACOs to coordinate Medicare fee-for-service patients must assist those most vulnerable to lapses of care coordination during care transitions. For example, limited English speaking populations may encounter challenges in finding bilingual providers. In addition, the many dialects of certain languages and technicality of medical language may make translations difficult. PAF has improved care coordination for migrant workers with its Mi Vida program. This program gives personal health records to migrant farmers so that subsequent health providers may review patient medical histories before a translator or bilingual provider is located.

- **ACOs are to communicate clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them.** This is an important criterion as people of all ages, races, incomes and education levels – not just people with limited reading skills or people for whom English is a second language – are affected by limited health literacy.¹⁸ Health literacy is a challenge for everyone. NPAF's companion organization, PAF has extensive experience in developing materials for patients that is understandable to them. PAF continues to refine that expertise as health literacy studies become more informative. NPAF believes that any information made available to consumers must be written in a manner that he or she can understand. This goes beyond simply writing at a sixth grade reading level, but also being careful about the use of complex sentence structure, the use of unnecessary medical terms and when certain medical terms are needed, including definitions and explanations. Concrete language must be in place to ensure easy navigation through the contract, even if it means giving explicit instructions where a specific treatment is being discussed without having to refer to another page. .

PAF welcomes opportunities to partner with HHS to assure this patient-centered criterion, and all such criteria, benefit patients.

- **ACOs are to have written standards for beneficiary access and communication and a process in place for beneficiaries to access their medical records.** NPAF recognizes the importance of beneficiary access to health information. It also recognizes that not all beneficiaries have equal access to electronic media. Beneficiaries who reside in rural areas may not be able to access electronic medical records, even though such records may exist. In addition, patients are not likely to have familiarity with the medical jargon found in patient records. NPAF suggests CMS encourage ACOs to allow for *meaningful access to and use of* their medical records as well as their personal health record, and not mere access to them. Meaningful access would include the availability of resources to explain the information in the medical record so that patients are informed of the care they have received. Patient resources should include, but not be limited to, hard copies of the medical record, personal health record, security-code accessible electronic medical records and a 1-800 helpline for access to a person who can explain medical terms. This information may assist with improving patient compliance to future medical advice provided. It also allows for both patients and providers to receive real-time sharing of health information.

- **ACOs must have internal processes in place for measuring clinical or service performance by physicians across the practices and use these results to improve care and services over time.** The process for measuring physician performance must take into account

¹⁸ Kutner, M., Greenberg, E., Jin, Y., & Paulsen, C. (2006). *The health literacy of America's adults: Results from the 2003 National Assessment of Adult Literacy* 9NCES 2006-483). Washington, DC: U.S. Department of Education, National Center for Education Statistics.

patient severity of illness. It must have a strong patient-protection focus such as the inclusion of a peer-review process that provides sanctions or termination for providers who do not deliver quality care as defined by nationally recognized entities with experience in defining quality care such as the American Medical Association or the Agency for Healthcare Research and Quality. ACOs must be able to provide evidence of precisely how the quality performance measures were utilized to improve care and services over time. Innovative practices in doing so should be shared with other ACOs, although provider-specific information should be removed.

Proposed Quality Measures for Use in Establishing ACO Quality Performance Standards

NPAF recognizes that many of the quality measures are process-oriented. While outcome measures may be difficult to achieve within a three-year timeframe, NPAF encourages CMS to incorporate a greater percentage of reasonable outcome measures. The National Quality Forum focuses on patient-outcome measures offering the greatest potential impact, such as common conditions, as well as gaps in measurement of patient-focused outcomes, and transitions across care settings. CMS should partner with NQF to develop appropriate outcome measures that can be tested nationally. In addition, CMS should perform provider cost-benefit analyses when identifying quality metrics. The Physician Group Practice estimates that on average, it costs about \$30,000 just to program a new quality metric. The required metrics should be prioritized in terms of their ability to produce valid and reliable information regarding patient care delivery relative to the cost to the provider.

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

Respectfully submitted,



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