



Regulatory Education and Action for Patients

● *Seeking Common Ground*

June 6, 2011

Donald Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

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

Dear Dr. Berwick:

On behalf of Regulatory Education and Action for Patients (REAP), we would like to thank you for the opportunity to comment on Proposed Rule CMS-1345-P, "Medicare Shared Savings Program: Accountable Care Organizations" published in the *Federal Register* on April 7, 2011.¹

REAP is an umbrella coalition comprised of patient advocacy groups whose goal is to strengthen current relationships and build new relationships with government agencies that have the responsibility for implementing provisions of the Patient Protection and Affordable Care Act, as amended, and to ensure that implementation of the Act's provisions is patient-centric. The unique experience and expertise of each REAP member organization allows REAP to provide the patient voice in a cross-disciplinary manner.

REAP's mission is to communicate issues to Federal and State regulatory bodies, Congress, health care insurers and others that regulate, develop, manage and/or impact health delivery, coverage, cost and availability of services to the United States population. REAP will, through its member entities, contribute information and perspectives regarding important health care decisions to a degree that has not been possible heretofore by individual health care advocacy groups in the regulatory arena.

REAP supports the concept of developing new health care models that will result in more comprehensive and continuous delivery of care with better patient outcomes and lower care delivery costs. We understand from conversations with the individuals/patients for whom we advocate and from case management interventions taken on their behalf, the difficulties that patients experience today because of fragmentation in our health care system. We believe our constituents would greatly benefit from a new care delivery model committed to the provision of evidence-based, coordinated care, the use of sophisticated electronic health records, and the delivery of patient-centric services designed to improve quality and outcomes while reducing cost.

¹ 76 *Fed. Reg.* 19527 (April 7, 2011).

We applaud the decision to allow Medicare to lead in the development of care delivery through organizations that will be accountable for all of their patients' Medicare Part A and B services, even if those services are provided outside the ACO. We appreciate that certain provisions of the Proposed Rule are intended to encourage participating organizations to change their approach to treating all of their patients – not just the Medicare beneficiaries that will be assigned the ACO for purposes of determining bonus payments.

We also would like to commend CMS for working with the Department of Health and Human Services Office of Inspector General and the Internal Revenue Service to ensure their notices requesting public comment on ACO-related issues would be published in the *Federal Register* on the same day the Proposed Rule issued. We note too that CMS coordinated with the Federal Trade Commission and the Antitrust Division of the Department of Justice on the publication of the joint "FTC and DOJ Proposed Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (Antitrust Policy Statement)." This type of inter-agency cooperation is unusual in our experience and it serves as a symbolic comment on the value being placed on coordination under the Shared Savings Program.

We have divided our comments on the ACO Proposed Rule itself by issue to facilitate your review of our input.

Encouraging Broad Participation

REAP believes in the potential added value of evidence-based, coordinated care delivered through an ACO to the individuals our member organizations serve. For that reason alone, we would like to see broad initial participation in the Medicare Shared Savings Program beginning next year. We would be delighted if the stated goal of having 10% of the Medicare fee-for-service population in ACOs next year could be achieved because robust uptake of the Shared Saving Program would offer more opportunity for the dissemination of ACO best practices applicable to a variety of settings.

We strongly urge CMS to consider how best to encourage the effective exchange of lessons learned from ACO operations about effective processes for functions such as developing and maintaining evidence-based guidelines, providing patient-centric care, ensuring appropriate care coordination, improving quality, and reducing costs. With additional guidance, providers not able to participate initially in the Shared Savings Program may begin to incorporate effective care delivery changes into their daily workflows and move toward a more clinically integrated practice model. Unfortunately, the Proposed Rule fails to address this aspect of ACO implementation even though it will be essential if new and improved approaches to care delivery developed by early adopters of the ACO concept are to spread throughout the health care system, making integrated care delivery models more accessible to patients.

We applaud the decision to allow Critical Access Hospitals (CAHs) that bill under Method II to form ACOs. The value of a revamped care delivery system should be available to Medicare beneficiaries who reside in rural and underserved areas as well as those in more populous metropolitan areas. Allowing the small hospitals prevalent in such areas to form an ACO should help with this objective. We would have liked to have seen Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs) afforded the same right as CAHs regarding ACO formation but we acknowledge the reimbursement system limitations that stand in the way. We recognize the Proposed Rule contemplates offering ACOs



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an enhanced share of any savings if they incorporate FQHCs and RHCs in their networks. Again, we recognize the value that ACOs could bring to the vulnerable populations served by RQHCs and RHCs.

We appreciate this accommodation but it does not, in our view, fully compensate for the fact that FQHC/RHC-centric ACOs will not be permitted. The fact that beneficiaries who receive all of their primary care services from the non-physician practitioners that staff many FQHCs or RHCs will not be eligible for assignment to an ACO because Social Security Act §1899(c) mandates that assignment be based solely on services furnished by M.D.s and D.O.s. only exacerbates the situation.

We note that at least one recently published issue brief has concluded that ACO Proposed Rule policies affecting FQHCs and RHCs effectively will exclude many patients who live in communities that lack primary care physicians and who must depend instead on health care teams and health centers from being assigned to an ACO.² We know such facilities treat high proportions of dual eligible beneficiaries so any modifications to the Proposed Rule that would enhance the role of FQHCs and RHCs and their non-physician practitioner staffs would address CMS' and REAP's concerns about incorporating dual-eligible beneficiaries to the maximum extent possible into the Shared Savings Program.

We are quite troubled by recent press reports that organizations in the vanguard of the ACO movement are unlikely to apply for ACO status under the Proposed Rule because of what those organizations consider to be a "long list of barriers that . . . need to be reconsidered."³ The situation is the same with the most successful of the organizations participating in the Physician Group Practice demonstration project on which the ACO legislation was based.⁴

We repeatedly hear three primary complaints about the risk-benefit balance under the Proposed Rule both from sophisticated players well experienced in clinical integration and from providers who would like to begin the process of moving to a better way of practicing medicine. We offer them for your consideration in light of reports that you and your staff view the regulations "as a series of 'dials and levers' that officials will continue to adjust to make ACOs 'plausible for all sorts of different potential

² Rosenbaum, S and Shin, P, *Medicare's Accountable Care Organization Regulations: How Will Medicare Beneficiaries who Reside in Medically Underserved Communities Fare?*, Policy Research Brief #23, The George Washington University School of Public Health and Health Services Department of Health Policy (April 2010), available at <http://www.beckerhospitalreview.com/hospital-physician-relationships/aco-benefits-may-not-reach-underserved-communities.html>.

³ Adams, R, *Model ACO Health Centers Skeptical of Proposed Rule*, CQ Healthbeat News (May 6, 2011) (indicating that the Cleveland Clinic, the Mayo Clinic, Intermountain Healthcare and the Geisinger Health System "have so many concerns with the proposed rule to create ACOs that they doubt that they will participate), available at <http://www.cq.com/doc/hbnews-3864730?wr=bzR2QWhQbmtjMGtJdidNRWZkVWBPdw>.

⁴ *Marshfield Clinic Leaning Toward Not Initially Participating in ACO Program*, Inside Health Policy (May 3, 2011), available at <http://insidehealthpolicy.com/201105032362714/Health-Daily-News/Marshfield-clinic-leaning-toward-not-initially-participating-in-aco-program/menu-id-212.html>.

sponsors throughout the country”⁵ Universally, providers seem to believe the proportion of savings to be returned to ACOs is insufficient, particularly in light of the risk that all ACOs would be required to bear in conjunction with other restrictions and limitation on the bonus calculation under the Proposed Rule. Many suggest that CMS adopt a savings sharing percentage more in line with the 80% share offered to participants under the Physician Group Practice (PGP) demonstration.⁶ They argue the higher level of provider sharing is necessary to defer the not inconsequential start-up and maintenance costs of operating an ACO. Modifying these barriers will lead to more rapid adoption and proliferation of this option for patients.

We hear concerns as well about the backward-looking, ACO-specific nature of the benchmarks proposed as surrogates for what expenditures would have been without the ACO initiative. Such benchmarks are seen as disadvantaging organizations that have already taken significant steps to improve efficiencies and reduce cost. They also disadvantage providers in lower cost of service areas. The use of concurrent benchmarks that compare expenditures for beneficiaries assigned to an ACO with those for similar risk-adjusted cohorts of unassigned beneficiaries in the same geographic area might be a solution that allows for a more balanced approach to assessing shared savings. As we understand it, CMS used such an approach in the PGP demonstration.

Clinical Trials

REAP is strongly committed to ensuring that payment systems do not stand in the way of patient access to treatments or the pace of innovation. We recognize that the use of evidence-based guidelines will be at the heart of ACO operations, but as we discussed above, we suspect an ACO Final Rule that bases bonus calculations on a comparison with concurrent benchmarks will be more compatible with the appropriate evolution of standards of care and better accommodate advances in technology.

REAP wants the patients we represent to have access to clinical trials and we continuously work to improve trial participation. We were surprised, given the importance of clinical trials to innovation, that the Proposed Rule was completely silent on the topic. We are also concerned that the inclusion of academic medical centers – many of which also are disproportionate share hospitals (DSHs)– in an ACO could put the ACO at a financial disadvantage since these centers are often where patients must go if they wish to enroll in a clinical trial.

We would like to see the Final Rule explain how clinical trials will be handled to avoid discouraging ACOs from appropriately referring patients to outside organizations for clinical trial purposes. One thought is that patients who elect to participate in clinical trials should be carved out from assignment to an ACO (and if concurrent benchmarks are used, from comparison groups) to eliminate any concerns that ACOs may have about trial costs undermining bonus payments. We also encourage CMS to think further about how to address the cost issues associated with the inclusion of DSHs in ACOs and about potential ways to adjust for the cost disadvantages of doing so.

⁵ *Berwick Defends Proposed Rules for ACOs*, Modern Healthcare (May 3, 2011), available at <http://www.modernhealthcare.com/article/20110503/BLOGS04/305039983&template=printpicart>

⁶ Kautter, J. et al., *Medicare Physician Group Practice Demonstration Design: Quality and Efficiency Pay-for-Performance*, Health Care Financing Review, vol. 29, no. 1 (Fall 2007), available on the CMS website at https://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_Demo_Design.pdf.



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For patients facing life-threatening conditions, their only treatment option may be through a clinical trial. Enrollment rates in clinical trials drive the speed of discovery and accelerate access to larger populations. Our Nation's science and access to care goals should not be at odds with one another.

Beneficiary Assignment

The Proposed Rule would assign Medicare fee-for-service beneficiaries to ACOs only when they receive the plurality of their primary care services from physicians with a specialty designation of internal medicine, general practice, family practice or geriatric medicine.

As we noted in our discussion above about the constraints facing the formation of ACOs in rural and underserved areas where non-physician practitioners furnish most of the available primary care services, the physician-centric approach to beneficiary assignment could deprive beneficiaries who reside in areas plagued by shortages of primary care physicians of the opportunity to participate in an ACO. We would like to see this problem addressed by the inclusion of physicians assistants, nurse practitioners and clinical nurse specialists in the list of professionals triggering beneficiary assignment to an ACO, but we understand that Social Security Act §1899(c) expressly restricts the basis for assignment to primary care services provided by M.D.s and D.O.

We are more concerned, however, about the decision to in the Proposed Rule to tie beneficiary assignment to the receipt of services only from physicians with what CMS considers to be a primary care specialty designation. This approach will further limit access to ACOs in rural and inter-city urban areas where such primary care doctors are in short supply.

Perhaps more importantly from the perspective of the individuals that REAP organizations represent, it also will preclude the formation and operation of specialty-specific ACOs such as those comprised of oncologists or other specialists who often function as the primary care providers for many of the patients they treat. Here, the statute clearly allows CMS the leeway to take a different tact by defining primary care services based solely on a list of procedure codes identifying outpatient cognitive services and not be grafting on the additional requirement that those primary care services be furnishes only by certain types of physicians. Doing so would, in our view, be more consistent with the legislative intent underlying Social Security Act §1899.

Social Security Act §1899(c) sets out the rules for beneficiaries assignment to ACOs – rules that are straightforward and unambiguous. It says CMS should:

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).

Subsection (h)(1)(A) defines an “ACO professional” for purposes of assignment as a physician as that term is defined in Social Security Act §1861(r)(1) – in other words, as an M.D. or a D.O.

Neither Social Security Act §1861(r)(1) or §1899(c) mention physician specialty. This is not an oversight. It is a reflection of Congressional intent. The Ways & Means report on section 1301 of H.R. 3200,⁷ the House predecessor to Patient Protection and Affordable Care Act (PPACA)⁸ §3022, which codified the Shared Saving Program at Social Security Act §1899, states:

The Committee believes that physicians, *regardless of specialty*, who play a central role in managing the care of their patient populations, and who are willing and able to be held accountable for the overall quality and costs of care for their patients across all care settings, should be allowed to form ACOs.

For example, the Secretary could permit the formation of ACOs that are principally composed of *primary care physicians whose specialties are oncology, cardiology, nephrology, or other specialties* that serve beneficiaries being treated for chronic conditions; physicians in the ACO would be held accountable for the overall quality and costs of care for beneficiaries, including care not directly related to the beneficiaries’ principle diagnoses.

(emphasis added).

The only mention of physician specialty in all of Social Security Act §1899 is in §1899(b)(2)(D), which deals with the eligibility requirements that CMS is to impose when it reviews applications from organizations interested in becoming an ACO. It stipulates that an ACO must include

sufficient primary care ACO professionals for the number of fee-for-service beneficiaries assigned to the ACO under the terms specified in §1899(c).

As we read Social Security Act §1899 in light of the report language, it requires that once the number and identity of beneficiaries assigned to an ACO have been determined *without regard to physician specialty* pursuant to §1899(c), CMS should make a separate determination about the sufficiency of *primary care ACO professionals* in the ACO. Notably, the definition of “ACO professional” in this section of the statute has been expanded beyond that used in §1899(c) to include both physicians and non-physician practitioners eligible to bill in their own right under the Physician Fee Schedule.

As the language in the Ways & Means report makes clear, even in §1899(b)(2)(D), Congress did not intend for CMS to interpret the term “primary care physician” to mean just physicians with the primary care designations selected by CMS as the basis for ACO assignment in the Proposed Rule. The report indicates that ACOs should:

[i]nclude a sufficient number of primary care physicians *regardless of specialty* for the applicable beneficiaries for whose care the group is accountable.

⁷ Report of the Committee on Ways and Means on H.R. 3200, 111th Congress, 1st Session, Rept. 111-299, Part 2, p 412.

⁸ Pub. L. 111-148 (March 23, 2010).



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(emphasis added).⁹ Given this, we can only conclude that the “primary care services” under §1899(c) that are to form the basis for beneficiary assignment to ACOs must be services identified by some set of procedure codes and not such services only when they are delivered by physicians defined by CMS as being primary care specialists.

The legislative history of Social Security Act §1899 provides further support for the conclusion that beneficiaries should be assigned to ACOs based on a defined list of primary care services. Both the Ways & Means report¹⁰ and the Energy and Commerce report¹¹ indicate that the Shared Saving Program is designed to build upon the progress of the PGP demonstration project. As CMS admits, that program defined primary care services based solely on a defined set of evaluation and management codes specifically to provide “an opportunity for specialists to take responsibility for ensuring that their patients’ primary care needs were being met.”¹² It seems improbable that Congress would, in the absence of legislative or report language guidance, expect CMS to propose a fundamental change in the process for assigning beneficiaries under a Shared Saving Program intended to be a direct outgrowth of the PGP demonstration.

CMS also attempts to support the physician specialty-based approach to beneficiary assignment by arguing that it is necessary to establish a parallel with the requirements of PPACA §5501.¹³ That provision of the law establishes an incentive payment for primary care services that are identified by a predefined set of procedure codes but recognized for the incentive payment only when they are provided by primary care practitioners. CMS states:

It is dubious whether the codes identified in section 5501 of the Affordable Care Act alone, when they are not provided by primary care doctors and other practitioners, truly constitute primary care services.¹⁴

We strongly disagree with CMS’ observation about the meaning of “primary care services” under §5501 and with its reliance on parallels between that section and Social Security Act §1899 to support its choice of specialty designations to define primary care services for purposes of the Shared Saving Program. The purpose of PPACA §5501 was to provide a financial incentive to induce more medical students to specialize in the primary care specialties. The Energy and Commerce Committee explained the provision in the House health reform legislation that ultimately became PPACA §5501 as follows:

⁹ *Id.* at p 408.

¹⁰ *Id.* at pp 411-12.

¹¹ Report of the Committee on Energy and Commerce on H.R. 3200, 111th Congress, 1st Session, Rept. 111-299, Part 1, p 515.

¹² 76 *Fed. Reg.* at 19564.

¹³ *Id.*

¹⁴ *Id.*

The provision would establish payment incentives in Medicare to promote primary care furnished by primary care practitioners. . . . A primary care practitioner would be defined as (1) a physician or other health care practitioner (including a nurse practitioner) who specializes in family medicine, general internal medicine, general pediatrics, geriatrics, or obstetrics and gynecology and has allowed charges for primary care services that account for at least 50% of the physician’s or practitioner’s total allowed charges under [the Physician Fee Schedule], as determined by the Secretary for the most recent period for which data are available, or (2) a physician assistant who is under the supervision of a practitioner described above.¹⁵

The discussion of the same provision by the Ways and Means Committee¹⁶ leads to the same unambiguous conclusion.

PPACA §5501 provides for a percentage add-on payment to the standard payment for primary care services defined by a set of procedure codes as a vehicle for paying a financial incentive to those physicians and practitioners who elect to go into primary care. This provision does not conflate primary care service codes with primary care designations and it does not justify the proposal to use physician specialty-based assignment under the Shared Savings Program. Rather, §5501 merely uses add-on payments to the primary care service codes that constitute the bulk of the codes billed by physicians in the primary care specialties to funnel extra money to the physicians and practitioners who choose those specialties as a way to encourage more medical students and advanced practice non-physician professionals to make such a choice.

In addition to the above discussion of Congressional intent about the appropriateness of revising the ACO assignment provisions in a way that will permit the formation of specialty-specific ACOs, we would like to point out that the types of specialists who tend to provide some or all of the primary care services receive by their patients (*e.g.*, oncologists, cardiologists, endocrinologists, rheumatologists, nephrologists) were trained and Board certified in internal medicine before they began their specialty training.¹⁷ We certainly see no reason why primary care services provided by a physician trained and certified in internal medicine should be precluded from consideration for purposes of beneficiary assignment under the ACO regulations – so long as they assume full responsibility for primary care services - just because that physician chose to obtain additional training in a subspecialty. If, however, you decide to continue tying beneficiary assignment to physician specialty when the ACO regulations are finalized, we strongly encourage you to clarify in that Final Rule that any specialist

¹⁵ Report of the Committee on Energy and Commerce on H.R. 3200, 111th Congress, 1st Session, Rept. 111-299, Part 1, p 526.

¹⁶ Report of the Committee on Ways and Means on H.R. 3200, 111th Congress, 1st Session, Rept. 111-299, p 418.

¹⁷ See American College of Physicians website describing the Internal Medicine Subspecialties at http://www.acponline.org/patients_families/acout_internal_medicine/subspecialties/. The description of “Medical Oncologist,” for example, states that: “Medical oncology is the subspecialty of internal medicine that focuses on treating cancer. . . .Medical oncologists must first complete seven or more years of medical school and postgraduate training and become board certified in Internal Medicine. Then, for an additional two years, they are broadly trained in all areas of oncology. Some medical oncologists also further specialize in specific types of cancer, such as breast cancer, lung cancer, prostate cancer, leukemia, or lymphoma.” Descriptions of the other Internal Medicine subspecialties are similar in that they all state that the starting place is board certification in Internal Medicine.



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initially trained and certified in internal medicine will be considered a primary care physician for purposes of beneficiary assignment.

In conclusion, REAP favors ACO assignment based solely on the provision of the plurality of primary care services identified using CPT codes without regard to physician specialty. We are convinced that this approach is what Congress intended when it drafted Social Security Act §1899 and that it is the approach required by the plain language of the statute. Further, it would allow patients who receive the plurality of their primary care services from specialists likely trained first in internal medicine, to be assigned to an ACO. We expect that a majority of patients added to the roles of those eligible for ACO assignment under the approach we support would have chronic, complex diseases of the type that would benefit from evidence-based, coordinated care delivery and offer great potential for cost savings. Restricting their assignment to ACOs by using a physician specialty approach to primary care seems counterintuitive if the objective is broad update of the ACO concept.

Beneficiary Choice

REAP applauds the notion of beneficiary choice. We see choice as being at the heart of the difference between accountable care and managed care. Moreover, we know from experience that choice is particularly valued by the individuals for whom we advocate. REAP hails the plan to require that beneficiaries be notified when a physician they are seeing is participating in an ACO. We are particularly pleased that ACOs will be expected to educate beneficiaries about the potential benefits, from both a quality of care and a beneficiary cost perspective, of receiving care under an ACO arrangement. We also expect that education to make clear that patients have no obligation to obtain all of their care from providers that are participating in or even working under contract with the ACO but, at the same time, to explain the value of staying “in ACO” from a coordination and quality of care perspective.

It is critical that beneficiary education about the ACO concept be effective. REAP recommends its comments to the Agency for Healthcare Research and Quality (AHRQ) in response to its “Request for Measures of Health Plan Efforts to Address Health Plan Members’ Health Literacy Needs” in this regard. A copy of those comments is attached as Exhibit 1 for each of reference.

REAP members would like to have the opportunity to work cooperatively with CMS to help with effective beneficiary education about ACOs. We believe that establishing a process for beneficiaries to obtain answers to questions about ACO participation from a source independent from their physician’s office would help encourage beneficiary participation, particularly by those beneficiaries with the types of chronic conditions that our organizations currently serve. Further, we think that such an outreach effort would benefit from the existing trust relationships that REAP members have with their patient constituencies.

We understand that beneficiaries have different value systems and beliefs and we respect the steps that CMS has taken in an effort to incorporate beneficiary privacy concerns into the Proposed Rule. We are,

however, torn by the tension between the obvious need that ACOs will have for claims level data and the right of beneficiaries to elect to keep this information private. We appreciate that ACOs will need the claims data since they are to be accountable for all of the Part A and B services that assigned beneficiaries receive even though they have no visibility into those services if they are received outside the ACO. We urge CMS to provide ACOs with aggregate cost data including information relevant to beneficiaries who opt-out of claims level data sharing under any circumstances. More broadly, we see the solution to the tension between the ACO's need for claims level data and the desire of for beneficiary privacy as education – education in which our member organization would like to participate.

We remain troubled from a privacy and choice perspective of the plan to provide ACOs with the names and basic demographic information about beneficiaries that would have been assigned to them if they had been ACOs in the prior three years. We question whether CMS actually has the legal authority to make such disclosures under the Privacy Act of 1974.¹⁸ We would argue that such a data release is not a “routine use” that is “compatible with the purpose for which [the data] was collected” since the information was provided to the Medicare program for the purpose of claims payment. We also see the provision of these names in advance as having the potential to undermine the objective of having ACOs provide the same level and type of care to all of their Medicare patients that is key to the proposed selection of retrospective instead of prospective beneficiary assignment. Restructuring the ACO benchmarks to use concurrent risk-matched control groups rather than backward-looking, ACO-specific comparison points would resolve this privacy issue in addition to addressing the innovation and “level playing field” concerns discussed above.

Retrospective v. Prospective Assignment

Prior to the publication of the Proposed Rule, REAP was concerned about the prospect of retroactive assignment of beneficiaries to ACOs because of the impact such an assignment process would have on beneficiary choice. Despite our commitment to freedom of choice, REAP is satisfied that the benefits of retrospective beneficiary assignment will likely outweigh any the concerns about choice that might remain because of the beneficiary notification, education and claims data-sharing opt-out provided for under the Proposed Rule. We know that retrospective assignment will encourage ACOs to provide the same level and type of services under consistent care delivery models to their entire patient population and we see this as a highly desirable goal. It also will work against any tendencies providers may have to focus only on the care of patients they know have been assigned to the ACO for the purposes measuring cost savings. Further, we have to believe that retrospective assignment is essential to the population of specialty ACOs (assuming the Final Rule permits them) since patients will not typically begin receiving their primary care services from a specialist until a triggering diagnose occurs at some point during a Shared Savings Program measurement year.

Quality Measures

ACOs are intended to improve the health and the quality of the health care delivered to individual beneficiaries cared for by ACO professionals while, at the same time, reducing Medicare Part A and B expenditures. As a result, reporting and performing well on quality measures will be integral to the receipt and size of bonuses available to each ACO under the Shared Saving Program. Making quality measures integral to the assessment of bonuses is essential to protect against stinting on care. In that

¹⁸ 5 USC §552a.



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sense, the comprehensiveness and appropriateness of the quality measures set is crucial to the success of the ACO concept.

The Proposed Rule details a set of 65 quality measures divided into five domains against which an ACO's performance and bonus potential would be assessed. All measures within a domain must demonstrate a score above the minimum attainment level determined by CMS for the domain to be eligible for shared savings. Although the Proposed Rule expressly allows for physician-centric ACOs that do not involve participation by a hospital, a significant number of the quality measures relate to inpatient care. Moreover, many of the quality measures specified in the Proposed Rule seem inapplicable to the types of patients that we envision seeking care through specialty-specific ACOs.

We appreciate that CMS believes it does not have the authority under the Administrative Procedures Act to add quality measures applicable to 2012 to the ACO Final Rule that have not been vetted in the Notice of Proposed Rulemaking. Rather, the Final Rule must include all or some subset of the proposed measures only. Our comments on the proposed quality measures reflect this reality.

We are aware of concerns that the proposed set of quality measures provides an insufficient basis for assessing ACO performance.¹⁹ They point out that the measures are more process oriented (39 of 65) than outcome oriented (26 of 65) and therefore not well aligned with the key goals of ACOs.²⁰ We do not disagree, but we appreciate that the measurement of quality is an evolving science. We expect there will be more reliable, tested outcome-focused measures in the future. We also understand that evidence-based practice (processes) lead over time to long-term patient benefit (outcomes). We urge CMS to strive to include a higher proportion of such tested outcomes measures in subsequent iterations of the ACO regulations, to regularly engage in the rulemaking process necessary to vet and incorporate more appropriate measures into the regulations, and to adopt approaches to the definition of ACO quality measurement that will allow the use of customized quality measurement sets by any specialty-focused ACO that is accepted into the Shared Savings Program. We suggest CMS consider applying the approach to reporting used to establish meaningful use of an electronic health record in the context of ACO quality measures by requiring all ACOs to report on certain generally applicable core measures and then permitting ACOs to select supplement measures for reporting that are applicable to their specific patient base.

We applaud the decision to select ACO quality measures that are standardized and tested. We appreciate the decision to rely upon measures that have been endorsed by the National Quality Forum or drawn from the Physician Quality Reporting System and the Electronic Health Reports Incentive Program. That said, because many of the individuals represented by REAP members are cancer patients,

¹⁹ *Avalere: Quality Measures May Be Insufficient in Gauging ACO Efficacy*, Inside Health Policy, available at <http://insidehealthpolicy.com/201104252361989/Health-Daily-News/Daily-News/avalere-quality-measures-may-be-insufficient-in-gaugin-aco-efficacy/menu-id-212.html>.

²⁰ *Id.*

we are quite troubled by the fact that none of the proposed quality measures are cancer-centric, a highly prevalent chronic disease and cause of death among Medicare beneficiaries. We would like to have seen the inclusion of measures – particularly outcomes measures – drawn from the American Society of Clinical Oncology Quality Oncology Practice Initiative (QOPI®) in the Proposed Rule. These measures are standardized, tested and applicable specifically to the treatment of cancer patients. There is a similar need for measures applicable to conditions of high prevalence, morbidity, and mortality to Medicare beneficiaries.

To the extent that cancer patients or other patients with different complex, chronic diseases are assigned to an ACO and considered for purposes of the bonus calculation, the absence of applicable specialty-specific quality measures raises concerns about the risk of stinting in terms of often expensive care services. After all, the ACO would be paid in part based on its performance on quality measures relevant only to subpopulations not in need of certain specialty services but in part also based on savings in overall Part A and B expenditures that include specialty treatment costs for assigned beneficiaries. Given the critical importance, in our view, of incorporating quality measures relevant to subpopulations, particularly those subpopulations with complex, serious chronic diseases, we fervently hope future iterations of the ACO regulations, including those applicable to 2013, will incorporate some measures drawn from QOPI® and other similar tested specialty-specific quality measurement sets as a tool for ensuring that assigned beneficiaries with complex, chronic conditions receive high quality care under the new ACO delivery model.

Patient-Centeredness

One of the key characteristics of services provided through an ACO is patient-centeredness. This reality is at the heart of REAP support for the ACO concept because it is reflective of our commitment to the individuals on whose behalf we advocate. CMS has proposed that ACOs meet the patient-centeredness requirement by addressing eight core requirements, all of which we endorse.

The first of the patient-centeredness requirements is the directive to conduct periodic beneficiary experience-of-care surveys and to use the results of those surveys to improve care over time. We note that such surveys must be well-designed, standardized and composed of field-tested questions if they are to provide meaningful, useful information. Part of the testing needs to focus on the appropriateness and effectiveness of the survey instrument for racial and ethnic minority populations. Further, experience suggests it will be difficult for ACOs to obtain a high enough response rate to experience-of-care surveys to support development of meaningful conclusions unless the actual survey process is removed from the providers in the ACO. We encourage CMS to explore the developing literature on the design and conduct of such surveys so that it can recommend appropriate resources to ACOs in the Final Rule.

The second of the patient-centeredness requirements tasks ACOs with ensuring patient involvement in governance by seating at least one patient representative on its governing board. The Proposed Rule questions whether it would be preferable to require a patient advisory committee instead or in conjunction with a patient advocate board seat. REAP favors having a voting patient representative on each ACO's governing body and also requiring each ACO to establish a patient advisory committee that will function like a focus group and an ombudsman to inform board discussions and particularly the vote of the board representative. Requiring an advisory committee allows for diversity of perspective and should permit the provision of more nuanced inputs to the governing body by the voting patient representative who sits on the board.



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The third of the patient-centeredness requirements obligates each ACO to have in place a process for evaluating the health needs of its assigned populations, including consideration of diversity in that

population, and a plan to address the identified needs. Particularly in light of the proposal for retrospective assignment of beneficiaries to ACOs, it seems more reasonable to ask an ACO to develop and implement plans to address the health needs of the entire Medicare or even the entire patient population that it serves. The inclusion of more outcomes measures in the set of quality measures applicable to ACOs would, in our view, facilitate compliance with this patient-centered requirement.

REAP applauds the focus on diversity. We view this focus as being consistent with the HHS Action Plan to Reduce Racial and Ethnic Health Disparities, which we wholeheartedly endorse. Providing incentives for quality care to vulnerable racial and ethnic minority populations is critical for improving patient and population outcomes and creating a high-value health care system that promotes equality. REAP is committed to these goals and suggests that CMS address diversity more directly by building one or more quality measures designed to assess the equality of care delivered to ACO beneficiaries into the Shared Savings Program quality measures set in 2013 and by taking steps to ensure that ACOs use patient experience-of-care surveys that have been properly assessed for validity when they are completed by minorities.

The fourth requirement for patient-centeredness tasks ACOs with having systems in place to identify high-risk individuals and processes and to develop individualized care plans for targeted patient populations, including integration of community resources to address individual needs. REAP encourages you to identify dual eligible enrollees and other frail elderly beneficiaries as specific populations for which every ACO must prepare an individualized care plan. Our experience working with this patient population has shown us that addressing the transportation needs of patients with chronic, debilitating or life-threatening diseases is critical. We urge you to call out that service expressly when you comment on the types of social services encompassed by the obligation to integrate community resources into the care planning process. We also view ensuring the provision of appropriate patient navigator services to patients with complex medical or social needs an element of this requirement that should be called out in the Final Rule.

The fifth patient-centeredness requirement dictates that ACOs should have mechanisms in place or under development to coordinate care and a process in place to electronically exchange summary-of-care information when patients transition to another provider or setting of care both within and outside the ACO in a manner consistent with meaningful use requirements under the Electronic Health Record (EHR) Incentive Program. REAP member organizations have long supported the implementation of EHRs because we are convinced they have significant potential to reduce medical errors and allow the operation of more robust continuous quality improvement programs that protect patients and improve care delivery. EHR use is consistent with the goals and objectives of ACOs and likely critical to the assessment of the multitude of quality measures that eventually will need to be in place to evaluate ACO performance and calculate quality-weighted shared savings bonuses. We appreciate the decision to

integrate the meaningful use requirements into the ACO program. That said, we would like to see the Final Rule explain the accommodations that will be available to ACOs that are unable to electronically exchange care coordination information with entities outside the ACO when such organizations lack the capacity to receive the information. Such accommodations will be important to protecting beneficiary freedom of choice under the accountable care model.

The sixth requirement for patient-centeredness stipulates that ACOs must communicate clinical knowledge and evidence-based medicine concepts to beneficiaries and their caregivers in a way that is understandable to them. We have learned from working with the individuals we represent that it is not sufficient to explain complex medical concepts and choices or expected patient behaviors only once. People grasp such information better if it is presented to them both orally and in writing. They need time to ask questions, to digest the information and to contemplate the meaning to them, in the context of their value systems and life choices, of various clinical options available. It is also important to deliver this type of information multiple times, and frequently on a periodic basis throughout an episode of care. ACO processes for patient communication need to incorporate plans for regular reinforcement of the information presented. Our comments attached in Exhibit 1 are also relevant to this issue.

Under the seventh patient-centeredness requirement, ACOs must have in place written standards for beneficiary access and communication with the ACO's clinical staff as well as a process by which patients can access their medical records. Given the focus on EHRs, we hope most ACOs will offer records access through online portals to willing patients. More importantly, it has been our experience that records access alone is not sufficient. Rather, patients often need someone to walk them through their record, explain the abbreviations used and discuss the meaning of unfamiliar clinical terms. For this reason, we are pleased to see that this patient-centeredness provision includes requirements both for access to records per se and to ACO staff who should be prepared to interpret those records upon request.

The eighth and last patient-centeredness provision directs ACOs to operate programs for measuring clinical and service performance and to use the findings from these programs to improve care, services and clinical integration over time. We recommend not only requiring ACOs to use the information they gather internally but also to establish electronic forums, blogs and other social media type mechanisms for ACOs to share best practices and to discuss less than successful approaches to help other ACO avoid similar mistakes. Because of the criticality, in our mind, of the dissemination of practical learning by ACOs, we suggest developing one or more measures to assess information sharing and to incorporate performance on these measures along with performance on more traditional quality measures into the calculation of the shared savings bonuses earned.

At-Risk Beneficiaries

Because Social Security Act §1899(d)(3) allows CMS to impose sanctions on ACOs that take steps to avoid caring for at-risk patients, the Final Rule needs to define that concept. CMS has proposed to describe at-risk patients as beneficiaries who have high risk scores on the CMS-Hierarchical Condition category risk adjustment model, are considered high cost because they have two or more hospitalizations or emergency room visits each year or have one or more chronic conditions or a recent diagnosis that is expected to increase cost (*e.g.*, cancer). REAP agrees with these descriptions. We suggest adding being a racial or ethnic minority or being a minor or disabled to the list.



Regulatory Education and Action for Patients

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Again, we appreciate the opportunity to share our perspective about ACOs with you. REAP members all stand ready to answer questions and provide any additional information about the patient groups for whom we advocate.

Respectively Submitted,

Alliance for Aging Research
Alpha-1 Association
Alpha-1 Foundation
ALS Association
American Association of Peoples with Disabilities
American Brain Tumor Association
American Kidney Fund
C-Change
COPD Foundation
Fight Colorectal Cancer
Friends of Cancer Research
Kidney Cancer Association
Leukemia & Lymphoma Society
LIVESTRONG – Lance Armstrong Foundation
National Alliance on Mental Illness
National Patient Advocate Foundation
Prevent Cancer Foundation
ZERO – The Project to End Prostate Cancer

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NPAF Founding Organization

Exhibit 1

REAP Comments on in Response to AHRQ's "Request of Measures of Health Plan Efforts to Address Health Plan Members' Health Literacy Needs:

October 22, 2010

Cindy Brach
Center for Delivery, Organization, and Markets
Agency for Healthcare Research and Quality
540 Gaither Road, Room 5129
Rockville, MD 20850

RE: Request for Measures of Health Plan Efforts to Address Health Plan Members' Health Literacy Needs

Dear Ms. Brach:

Regulatory Education and Action for Patients (REAP) would like to thank you for the opportunity to respond to your request for Measures of Health Plan Efforts to Address Health Plan Members' Health Literacy Needs. REAP's mission is to communicate issues to Federal and State regulatory bodies, Congress, health care insurers and others that regulate/develop/manage and/or impact health delivery, coverage, cost and availability of services to the United States population. REAP will, through its member entities, contribute information and perspectives regarding important health care decisions to the degree that has not been possible heretofore by health care advocacy groups in the regulatory arena.

REAP is an umbrella coalition comprised of patient advocacy groups whose goal is to strengthen current relationships and build new relationships with government agencies that have the responsibility for implementing provisions of the Patient Protection and Affordable Care Act, and to ensure that implementation of these provisions is patient-centric. The unique experience and expertise of each REAP member organization allows REAP to provide the patient voice in a cross-disciplinary manner.

In taking into consideration the concerns that exist regarding the ability of consumers to understand instructions conveyed to them by their health care providers, REAP believes that even the most basic communication elements of health care services need to be examined. 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.ⁱ

Consumers who are enrolled in group health plans benefit from informational brochures and communication items that are generally prepared and written in a standardized format. While this may not markedly enhance the readability of the content, it at least organizes the information in a consistent manner for consumers. Material presented as such may not be available from small group practices or individual practitioners not associated with large and well-capitalized health plans. Unfortunately, the information conveyed by any health care provider, whether associated or not with a large health plan, is not always understood by consumers. According to research from the U.S. Department of Education, only 12 percent of English-speaking adults in the United States have proficient health literacy skills.ⁱⁱ This



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leads to consumer frustration, but more importantly, it can lead to consumer decisions that do not support positive health outcomes or can affect consumer safety.

As health care reform continues to be implemented, the number of consumers seeking information on contract language and interpretation will continue to increase. In order for many reform programs to be successful, we believe 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. Unfortunately, many patients do not read their plan language until they are confronted with a medical denial and/or a large medical bill, mainly because the plan language is too long and confusing.

It is also important to provide a foundation for the information that is being imparted i.e., explaining at the outset of the written communication what will be covered in the material and why it is important to be understood and followed. It is important that necessary plan communication be furnished in a one paragraph missive as much as it is in a multi-page communication. Examples interspersed throughout communication pieces will enhance readability and enable the uninformed consumer to better understand the information.

Increased customer support is needed at the insurer level. Some find that written and oral information is neither always accurate, nor is it clearly understandable. Telephone inquiries that are entered into a computer database enhances consumer needs while at the same time will enable the insurer to provide more efficient documented service that supports the information furnished, and the rationale for the information. We suggest that despite their best intention, some consumers are still finding it difficult to understand the specifics of their health plan.

Qualifying events provide an opportunity for insurers to communicate necessary information to consumers, and provide them a similar opportunity to pose questions to their insurer regarding the specifics of the provisions of their particular plan. Policy information, and coordination of benefits, are confusing to many and as these qualifying events occur, insurers that are proactive in their communication will be able to allay concerns by communicating often and in clear language. We suggest that all plans, if not already doing so, communicate with consumers with cooperation of their employers during all phases of working life to include entry to employment, open enrollment periods, qualifying events, disability leave and retirement.

Consumers need to receive information in writing that explains their options for continued insurance whether through retirement or COBRA. When employers provide written information to consumers, we

suggest that the documentation be distinctive in nature so that consumers are alerted to the fact that the impending action is unique and not of a routine nature. We suggest that employers require signature confirmation to acknowledge that the person has been advised of his or her benefits and how it applies to their specific situation. This signed statement will explain in detail what he or she has been advised. We recommend that information be added to COBRA paperwork that explains coordination with other insurance products, especially Medicare.

When plan questions arise and a copy of a plan is desired, some consumers are being referred by some insurers to their employers. As a result, some consumers are not able to get answers to their questions from their employer, since employers are not as familiar with the specifics of the plan language as are insurers. We suggest that insurers take a more active role in providing plan language to consumers and in fielding their questions since they are best equipped to answer them. Developing joint Q&As that address common questions for multiple insurance plans, and specifying a process that enables both insurers and employers to respond to specific one-time questions, would help them communicate collaboratively and more effectively with consumers.

The appeals process in its entirety can be extremely difficult for consumers to understand. Process elements that are particularly confusing include the number of appeals that are allowed, the appeal deadlines and how appeals can be lodged. A detailed explanation about the appeals process will enable consumers to feel more empowered. When a denial of coverage, for example, is received by a consumer, he or she will be better prepared to file an appeal if important information has already been made available. Consumers are taking advantage of online information to a greater degree than ever before, and the use of “real time” question and answer portals will enhance their ability to provide appeals information that the insurer needs in order to adjudicate the claim.

We thank you for the opportunity to comment. We would be pleased to respond to any questions about our recommendations that may arise regarding health literacy in the future.

Respectfully submitted,

The ALS Association
American Brain Tumor Association
C-Change
Friends of Cancer Research
Kidney Cancer Association
The Leukemia & Lymphoma Society
National Patient Advocate Foundation
Parkinson’s Action Network
Susan G. Komen for the Cure

ⁱ U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion (2010). National Action Plan to Improve Health Literacy. Washington, DC, page 4

ⁱⁱ 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.