



December 3, 2010

Donald Berwick, MD, MPP, FRCP
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Ave. SW Room 445-G
Washington, DC 20201

RE: CMS-1345-NC Medicare Program; Request for Information Regarding Accountable Care Organizations and the Medicare Shared Savings Program

Dear Dr. Berwick,

Thank you for the opportunity to comment on the Request for Information Regarding Accountable Care Organizations and the Medicare Shared Savings Program. America's Health Insurance Plans (AHIP) is the national association representing nearly 1,300 health insurance plans providing coverage to more than 200 million Americans.

Under the Patient Protection and Affordable Care Act (ACA), CMS is required to implement a Medicare Shared Savings Program to promote the formation and operation of accountable care organizations (ACOs). The success of the program will depend on whether the agencies create a sound regulatory framework that does not result in consumer harm. Creating an appropriate framework is particularly important since the impact of the regulations will likely extend to the private sector as ACOs participating in the public program will likely seek commercial contracts as well.

AHIP and its members support the ACO program as it encourages alternative payment models that may help to transform the health care system. In fact, health plans have already been partnering with providers and others across the country to test and implement innovative models to achieve quality, care coordination and affordability goals. As the agencies work through various policy and design issues, our members are ready to serve as a resource to develop solutions that address structural, policy, technical and legal challenges that will need to be addressed to ensure the development of programs that fulfill the promise of the legislation.

In this letter, we provide answers to the specific questions posed in the Request for Information, which address solo and small practice provider participation and financing; patient attribution; patient and caregiver experience of care; patient-centeredness criteria; quality measures; and payment models.

The important questions posed by the Request for Information should be considered in a broader context, taking into account current marketplace dynamics as well as the intended goals of the Medicare Shared Savings Program and the Center for Medicare and Medicaid Innovation (CMMI). CMS should consider, for example, why ACOs established under the Medicare Shared Savings Program should potentially be granted special antitrust exemptions that have not been



December 3, 2010

Page 2

available to ACO-like entities currently operating in the commercial market, particularly when such exemptions have the potential to undermine competition.

As a result, at the outset of this letter, we also identify key risks and offer specific recommendations that CMS should consider to avoid disruption in the marketplace and prevent other unintended consequences. These risks include the potential for:

- Higher prices for consumers due to increased provider market power and reduced competition;
- Higher costs for consumers receiving care in the commercial market due to cost-shifting;
- Overuse, misuse or underuse of care due to broad waivers from fraud and abuse laws (e.g., Stark law, Anti-kickback statute, federal civil money penalty laws);
- Reduced quality and access, and increased costs for consumers if less stringent consumer protection standards apply to ACOs; and
- Failure of ACOs to meet quality and cost goals due to inadequate clinical integration.

While we recognize that the agency would like to encourage the formation of ACOs, we believe that certain recommendations set forth by some stakeholders (e.g., antitrust exemptions and fraud and abuse waivers) may undermine the goals of the program. We believe that protecting consumers from unintended higher costs and reduced quality should be the agency's first priority.

I. Key Recommendations to Help Ensure that Consumers Receive Comprehensive, High Quality, Patient-Centered, and Affordable Care

ACOs should not amass market power.

Key issues need to be considered and addressed by regulators and others to ensure the regulatory structure of ACOs does not result in reduced competition and higher prices, and negatively impact quality, safety, and access for consumers. For example, it is critical that HHS and the antitrust enforcement agencies consider whether the Medicare Shared Savings Program will result in the creation of provider market power (i.e., creating a provider network or hospital chain that insurers "must have" in their networks to market a product to consumers and employers). There is a substantial body of evidence, from government agencies, academics and others, of the harmful effect on consumers of provider consolidation that creates market power. Such market power leads to higher costs and, in spite of the purported justifications for such consolidations, does not appear to have resulted in improved quality. To help ensure that the Medicare Shared Savings Program and the movement to ACOs do not make an existing problem worse, the agencies should prohibit entities with market shares above a certain level from participating in the Medicare Shared Savings Program. Additionally, ACOs should be required to report quality and price metrics to CMS and the antitrust agencies. The antitrust agencies may use such information as part of their enforcement responsibilities under the antitrust laws.



December 3, 2010

Page 3

The agencies also need to consider carefully assertions made by providers and others that antitrust relief in some form (exemptions, safety zones or otherwise) or additional antitrust guidance is needed to provide hospitals, physicians and other health care professionals with sufficient incentives to participate in ACOs. Currently, there already exists substantial antitrust guidance with respect to joint ventures. This guidance includes the Statements of Antitrust Enforcement Policy in Health Care, the “Improving Health Care: A Dose of Competition” report, FTC advisory opinion letters, Department of Justice Business Review letters, FTC and DOJ enforcement actions, and speeches by agency officials.

The agency should encourage the alignment of public and private sector initiatives to avoid cost-shifting.

Given that the intent of ACA is to reduce the health care cost trend in both the public and private sectors, it is critical that CMS does not create incentives for ACOs to achieve savings in federal programs by increasing costs in the private market. To avoid this unintended consequence, we urge CMS to: (1) establish specific commercial rate metrics for participating ACOs that are tied to an objective benchmark (e.g., Medicare reimbursement rates); (2) require participating ACOs to report on those metrics before and during their participation in the program; and (3) tie any shared savings that participants receive to savings achieved in both Medicare and the commercial sector. This is necessary to achieve the intent of ACA by basing the savings achieved across all payers, not solely on a Medicare-only basis.

ACOs should not be used to undermine the important consumer protections by the fraud and abuse laws.

Some providers have suggested that concerns about violating fraud and abuse laws (e.g., Stark law, Anti-kickback statute, Federal civil money penalty laws) will be a potential barrier to the formation of ACOs, and that HHS therefore should waive the requirements of these laws. Broad exemptions from fraud and abuse laws are neither necessary to the success of the Medicare Shared Savings Program, nor likely to benefit patients. Instead, such exemptions would create significant risk of patient harm by undermining the protections offered by such laws against arrangements that result in inappropriate and unnecessary treatment. Such exemptions are unnecessary because the ACA itself grants the Secretary waiver authority as necessary on a case-by-case basis to achieve the goals of the program.

Therefore, we recommend that the agency avoid utilizing broad exemptions or blanket waivers. Instead, the agency should ensure that the program goals are being met, while allowing entities seeking to participate in the program the opportunity to simultaneously seek a waiver with respect to planned activities they have identified as potential impediments to their achievement of program goals. No entity would be required to seek such a waiver to participate in the program, and program participation itself would not constitute a waiver, but a wavier process would be made available to entities on an expedited basis. Any entity seeking such a wavier



December 3, 2010

Page 4

would need to provide information to the Secretary sufficient to: (1) identify the activities that raise potential issues under the fraud and abuse laws; (2) the reasons that the potential issues should not raise concerns in this instance; and (3) the necessity of a waiver to achieve the goals of the program. In addition, the information should include a certification that it is not using Medicare Shared Savings Program payments to induce the referral of patients outside of the program.

The Secretary could commit, to provide within a certain timeframe: (1) a narrow waiver based upon the specific request and accompanying information; (2) an indication that it will not provide such a waiver; and (3) a response that it cannot grant such a waiver without additional information. Any waiver should be for a limited time period with renewal favored if shared savings are achieved. Both the request (with accompanying information) and the Secretary's response should be public, to allow interested parties to provide relevant information to the Secretary as appropriate and to allow all parties to benefit from the base of knowledge generated by the process.

If ACOs perform functions typically performed by health plans, they should be subject to the same consumer protection standards to ensure a level playing field.

It is likely that ACOs will be performing various functions which are typically performed by health plans and other entities (e.g., assuming, allocating and managing risk to ensure financial stability and/or managing networks to ensure that patients can choose from providers that meet high standards). If ACOs – including those that may operate in the Exchanges – perform these functions, they should be subject to the same consumer protection standards which plans are required to meet. These standards include financial requirements (e.g., capital and solvency requirements); network adequacy requirements; filing, reporting & disclosure requirements; and quality improvement requirements, including accreditation standards. If ACOs are not subject to these same requirements, consumers receiving care from an ACO, may have less access to care, receive care of a lesser quality, be faced with increased costs, and/or be more vulnerable to discontinuation of coverage if unforeseen events occur, such as a flu pandemic or similar disaster impacting the health care system.

ACOs should be required to meet certain requirements to increase their likelihood of success.

In developing rulemaking for the Medicare Shared Savings Program and CMMI, CMS should consider certain key criteria that ACOs should meet to best ensure the success of these programs. These criteria include:

- The infrastructure to produce improvements in population health as well as individual patient outcomes (e.g., care coordination, risk assessment, and patient outreach);
- IT capabilities to allow for the performance of clinical, operational and administrative functions (e.g., provider exchange of health information);



December 3, 2010

Page 5

- Adequate networks that allow patients timely access to most clinical services necessary for coordinated and comprehensive care;
- The ability to assess performance using evidence-based outcomes, process and patient experience/satisfaction measures as well as episode and per capita cost measures;
- Accountability for the care of a sufficient number of individuals to ensure an appropriate sample size and ensure that an ACO has the capability to effectively and efficiently manage a range of diagnoses and diseases;
- Investment in adequate financial and human resources to ensure that ACOs can provide appropriate and timely access to clinical and administrative support;
- The ability to provide patients with useful provider performance data on quality, cost and patient experience at the individual hospital and physician level as well as at the network level; and
- The ability to implement or transition to payment models that align incentives and are effective at eliminating the delivery of fragmented care, and reducing overuse, misuse and waste in the system.

II. Answers to the Specific Questions Outlined in the Request for Information

What policies or standards should we consider adopting to ensure that groups of solo and small practice providers have the opportunity to actively participate in the Medicare Shared Savings Program and the ACO models tested by CMMI?

In establishing policies and standards for the Medicare Shared Savings Program, CMS should encourage a variety of different ACO models to help service the needs for Medicare beneficiaries, including physician-hospital organizations, physician group practices or IPAs that include physicians of a single specialty (e.g., primary care) or multiple specialties, or models formed by or in partnership with health plans.

While we support the ability for solo and small practice providers to actively participate in such programs, not all physician practices may be ready to participate in the Medicare Shared Savings Program. The adoption and use of health information technology appears to be one of the key limiting factors. The ability of smaller practices to virtually link together as a unit, sharing clinical and administrative data, evidence-based guidelines and accountability may offer some physician practices an opportunity to become an ACO. The experience of IPAs – which can help inform CMS as it develops its rules – has shown that their success may depend on local market dynamics. Additionally, there is a strong need for a governance structure with physician involvement.

Although there have been assertions that there are antitrust barriers to prevent solo and small practice providers from integrating across practice sites and meet the requirements for an ACO, health plans currently have provided solo and small practices with technical assistance to allow



December 3, 2010

Page 6

them to virtually integrate and care for a population of patients. As noted previously, we believe that there already exists substantial antitrust guidance with respect to joint ventures and therefore, no additional antitrust guidance or exemptions are necessary.

Many small practices may have limited access to capital or other resources to fund efforts from which “shared savings” could be generated. What payment models, financing mechanisms or other systems might we consider, either for the Shared Savings Program or as models under CMMI to address this issue? In addition to payment models, what other mechanisms could be created to provide access to capital?

As stated above, effective and efficient delivery of care to Medicare beneficiaries will require ACOs to establish a robust infrastructure. Currently, the capacity of different provider organizations to engage in activities such as care coordination, patient engagement, and analysis of data to identify quality improvement opportunities varies within and across geographic areas.

Typically, the presence of a robust infrastructure is driven by the size of the provider organization as larger organizations may have greater access to capital markets. Therefore, we recognize that many small practices may have limited access to capital or other resources to fund quality improvement efforts that can help enable an ACO to meet “shared savings” goals. CMS should consider providing different levels of financial support to help sustain key infrastructure until an ACO can access capital in the private market. Financial support should be need-based and primarily given to qualified underserved areas and safety net providers. An ACO that receives financial support should receive a reduced shared savings amount, offset by the financial support that it received (e.g., the ACO could only receive 50% of shared savings if it receives financial support).

The process of attributing beneficiaries to an ACO is important to ensure that expenditures, as well as any savings achieved by the ACO, are appropriately calculated and that quality performance is accurately measured. Having a seamless attribution process will also help ACO’s focus their efforts to deliver better care and promote better health. Some argue it is necessary to attribute beneficiaries before the start of a performance period, so the ACO can target care coordination strategies to those beneficiaries whose cost and quality information will be used to assess the ACO’s performance; others argue the attribution should occur at the end of the performance period to ensure the ACO is held accountable for care provided to beneficiaries who are aligned to it based upon services they receive from the ACO during the performance period. How should we balance these two points of view in developing the patient attribution models for the Medicare Shared Savings Program and ACO models tested by CMMI?

Attribution refers to the assignment of responsibility for provision of specific health care



December 3, 2010

Page 7

services and related patient outcomes for a patient to providers. For full accountability and to work operationally, the methodology for assigning and attributing patients to providers needs to be assigned at the formation of ACOs and be clearly understood by both patients and providers.

There are three main options that can be applied in attributing patients to ACOs: (1) prospective attribution or attribution at the beginning of the performance period; (2) retrospective attribution at the end of the performance period; and (3) prospective attribution with periodic reconciliation of assignment to account for patient turnover. Options one and three are better aligned with the goals of ACOs. ACOs and their participating providers should be aware of the patient population for which they are accountable so that they can deliver needed health care services to achieve optimal patient outcomes. Option two would not provide ACOs with the same incentives to manage and coordinate individual patients' care.

Comparing options one and three, option one has limitations as it may not account for turnover of patients during the performance period. Therefore, we recommend that CMS consider the use of prospective attribution with periodic reconciliation. Under this approach, patients would be assigned to an ACO at the beginning of a performance period based on, for example, two years of retrospective claims data. Both providers as well as patients would be informed of the assignment and patients would have the opportunity to "opt out" of the ACO. There would be periodic updates to the assignment based on either patients entering or exiting an ACO resulting from newly eligible Medicare beneficiaries, beneficiary relocation, death, etc. The shared savings that would accrue to the ACO should be calculated at the end of performance period and should be based on achievement of clearly defined quality and cost performance standards.

An issue often raised in conjunction with patient attribution is whether an ACO should be held accountable for any patient's care provided outside of the ACO. Given that ACOs seek to maintain adequate networks and provide patients with access to clinical services necessary for coordinated and comprehensive care, including highly specialized care, ACOs should be held accountable for all care, and for the total costs of all care, provided to their patients. If there are circumstances when appropriate specialized care is not available within the ACO network, ACOs and participating providers should still be held accountable for the sharing of clinical information with the external provider, the coordination of care, and the appropriate follow up care once the patient returns to the ACO network. While it may be challenging for ACOs to effectively influence patient care provided outside the ACO network, doing otherwise would defeat the key goals of ACOs which are focused on comprehensive, patient-centered care.

Finally, we recognize that attribution is a fundamental, complex issue that may require further testing and analysis. Evaluation of attribution methods to examine impact on patient outcomes and reliable measurement, and guard against unintended consequences needs to be considered during the early phases of the programs.



December 3, 2010

Page 8

How should we assess beneficiary and caregiver experience of care as part of our assessment of ACO performance?

The assessment of beneficiary and caregiver experience of care is essential to an ACO's success. While patient experience and satisfaction survey tools and approaches have been developed by a number of organizations, there does not appear to be one approach that by itself is sufficient to assess experience of care received through an ACO. For example, AHRQ has developed patient experience tools for assessing hospital and clinician groups, but they do not assess care experience along the continuum of care. In addition, a number of organizations, including the National Committee for Quality Assurance, TransformMED, and the California Cooperative Healthcare Reporting Initiative are using different approaches to assess patient experience, but such surveys are primarily focused on the design of patient centered medical homes.

We encourage CMS to work with AHRQ and other experts to develop a survey instrument that assesses beneficiary and caregiver experience and builds upon the best available tools. In developing a measurement instrument, various domains of patient-centered care should be considered, including patient engagement, shared decision-making, quality of care, patient safety, and management of coordination of care. The instrument should provide useful and actionable information that can be used to better inform patients, caregivers, and physicians and improve effectiveness, efficiency and patient-centered care.

The Affordable Care Act requires us to develop patient-centeredness criteria for assessment of ACOs participating in the Medicare Shared Savings Program. What aspects of patient-centeredness are particularly important for us to consider and how should we evaluate them?

The Affordable Care Act requires CMS to develop patient-centeredness criteria for assessment of ACOs participating in the Medicare Shared Savings Program. Currently, patient-centeredness is defined differently by different stakeholders. CMS should work with AHRQ and other experts to develop patient-centered criteria. In developing patient-centered criteria, the following broad categories should be addressed:

- promoting patient engagement;
- promoting self and life management;
- encouraging shared decision-making;
- addressing cultural, ethnic, racial and linguistic needs of the patients
- promoting holistic care which addresses all aspects of an individual
- reducing behavioral risk;
- identifying and eliminating barriers to care (e.g., transportation, caregiver issues)
- improving the quality of communication between patient and providers;
- addressing disparities in care;
- addressing issues related to health literacy; and
- seeking to improve individual outcomes related to patient care.



December 3, 2010

Page 9

In order for an ACO to share in savings under the Medicare Shared Savings Program, it must meet a quality performance standard determined by the Secretary. What quality measures should the Secretary use to determine performance in the Shared Savings Program?

Quality measures and patient outcomes are key elements of the Medicare Shared Savings Program, defining the standards by which performance will be evaluated and incentives determined. The availability and use of reliable and actionable measures is critical to the success and sustainability of the program. In selecting measures for the Shared Savings or CMMI-led programs, CMS should ensure that quality of care is measured along the care continuum with a focus on patient outcomes. Clinical domains of measurement should include prevention as well as treatment of common chronic conditions. Process measures, while helpful in identifying opportunities for practice improvement, may be less useful to patients because they do not assess patient experience and generally do not provide relevant information that will help patient decision-making and choice of provider. Measures selected for the program should address each component of the Triple Aim and be consistent with the six dimensions of quality care outlined by the Institute of Medicine (safe, effective, patient-centered, timely, efficient, and equitable).

CMS can build upon the measure set implemented in the Medicare Physician Group Practice Demonstration (PGP). The PGP measures are based on evidence-based best practices for chronic disease and preventive care. This core measure set should be further expanded to include patient outcome and safety measures that evaluate different care settings, such as physician offices, hospitals, and post-acute care. Patient outcomes and safety measures should focus on readmissions, hospital and healthcare acquired conditions, preventable complications, and emergency department use. Finally, shared savings requires that per capita and total costs of care are calculated and reported as part of the program.

To best ensure success, CMS should consider implementing a phased approach that, as the program matures, raises performance standards and promotes the evolution of measures and activities that both improve patient outcomes and reduce overuse, misuse and waste in the system. This approach needs to promote accountability in the ACO program that is comparable to what is required in the Medicare Advantage program. Such an approach will provide ACOs with incentives to improve performance, and at the same time, ease transitions for ACOs by setting realistic goals.

What additional payment models should CMS consider in addition to the model laid out in Section 1899(d), either under the authority provided in 1899(i) or the authority under the CMMI? What are the relative advantages and disadvantages of any such alternative payment models?

There are a variety of payment arrangements that CMS can consider in implementing its Medicare Shared Savings Program and the CMMI. Payment arrangements that better align



December 3, 2010

Page 10

incentives would be more effective at eliminating the delivery of fragmented care, and reducing overuse, misuse, and waste in the system. For example, beginning in year three, ACOs should be able to transition to shared risk payment models, such as global population payment arrangements with additional incentives for providers that meet quality and cost benchmarks. Entities that participated in the PGP demonstration may be able to accept downside risk before year three given that they already have appropriate infrastructures in place. Introduction of shared risk over time through use of penalties for poor performance, rewards for meeting established benchmarks, or partial or global payment arrangements can help ensure effective and efficient care.

It is critical that before implementing any of these payment arrangements, CMS considers possible implications of different payment arrangements and uses the CMMI to test and evaluate alternative payment models in their ability to influence provider behavior. For example, previous experience has demonstrated that some physician practices were not equipped to handle financial risk and allocation. Such experience demonstrates that providers need to have the appropriate infrastructure and business tools to move from shared savings to shared risk.

Two key issues relating to payment arrangements that CMS will need to address as it develops its rules with regard to the Medicare Shared Savings Program are the threshold that ACOs need to meet for accruing shared savings and the shared savings amount that ACOs will receive once they meet the threshold. We offer the following recommendations on these two issues.

- **Threshold for accruing shared savings.** The threshold for shared savings can be set equal to the CMS PGP demo or higher requiring the ACOs to meet a higher level of performance. Recognizing that at program inception not all ACOs may be able to meet the high performance standards, CMS should consider a phased approach to implementation, in which the performance expectations are revised upward over time. Such an approach would ensure that the ACOs have the time to build their needed infrastructure to meet the higher performance standards. It is important that the threshold be meaningful and helps distinguish between sustained and “true” improvements and random variations in performance.
- **Size of incentive.** The size of the incentive will play a critical role in influencing provider behavior. Size of the incentive will depend on various factors such as the share of the savings that an ACO accrues beyond the threshold. We initially recommend the use of a cap on bonuses and the elimination or raising of the cap over time as the program matures. Providing a greater share of savings to the ACOs can ultimately benefit the Medicare program by ensuring that the ACOs operate in an effective and efficient manner. In the alternative, CMS can consider providing a graduated share of savings that vary with the level of performance on quality and cost measures.

Health plans stand ready to collaborate with CMS and to share lessons learned from their experience implementing innovative payment and care delivery models. We encourage the



December 3, 2010

Page 11

Secretary to take advantage, to the fullest extent possible, of the existing efforts and infrastructures that have already been established by health plans and others within the private sector as well as other public sector programs, such as the Medicare Advantage program, that are widely viewed as successful. Additionally, HHS, providers, and other stakeholders should recognize the critical role which health plans can play to support delivery and payment reform efforts. Among other things, plans have the experience and infrastructure to: facilitate population health management; provide advanced data capabilities needed for efficiently performing clinical, operational and administrative functions; manage networks to ensure that patients have choices of high quality providers; and manage financial risk.

Thank you for the opportunity to offer comments regarding accountable care organizations and the Medicare Shared Savings Program. We believe using alternative payment models is an important step forward in achieving a reformed health care system and we applaud the agency's efforts to ensure that Americans receive consistent, quality, safe and affordable care.

Sincerely,

A handwritten signature in cursive script that reads "Carmella Bocchino".

Carmella Bocchino

Executive Vice President