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Donald Berwick, M.D.
Administrator
Centers for Medicare and Medicaid Services
Attention: ACO Legal Issues
Mail Stop C5-15-12
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Supplemental Comments on Medicare Shared Savings Program

Dear Dr. Berwick:

We are attorneys specializing in the representation of hospitals and physician groups in the suburban and rural areas throughout the Midwest. We provide consulting services to help these providers identify and prepare for opportunities and challenges presented by health care reform.

We appreciated the opportunity to attend the FTC/CMS ACO workshop on October 5 in Baltimore, and we have carefully considered the written comments submitted in conjunction with that meeting. We also participated in the CMS Region 7 ACO listening session on October 14 in Kansas City and have had conversations with numerous providers concerning their understanding, expectations, and fears relating to health care payment and delivery system reform. It is from this perspective we offer the following supplemental comments for CMS' consideration in drafting the Medicare Shared Savings Program ("MSSP") regulations.

I. CONTEXT FOR ACOS

To say the ACO model has garnered significant interest in the health care industry would be a gross understatement. Providers appreciate the MSSP as the first step toward broader payment and delivery system reform. To the extent that the road to reform is perilous and the ultimate destination shrouded, however, providers will be reluctant travelers and the momentum for such reform may be lost.

In drafting its proposed regulations, we urge CMS to articulate its long-term vision for payment and delivery system reform and describe how the MSSP fits into that vision. For example, CMS and ONC in publishing the final Stage 1 meaningful use regulations laid out an overall strategy for widespread adoption of HIT/HIE, through the future point in time at which providers will be penalized for failure to achieve meaningful use. There remain significant details to be addressed in later regulations, but providers understand and can plan for what lies ahead. This would not have been possible if the agencies had published the Stage 1 regulations in a vacuum without any mention of Stages 2 and 3 and the incentives (and eventual penalties) associated with them. Far fewer providers would be willing to invest in meaningful use with only the promise of one year's incentive payments.

The MSSP is a reward for those providers who collaborate to provide high-quality care in a cost-effective manner. Although these rewards may appear small at present, CMS can enhance the apparent value of the MSSP reward by placing a future value on coordinated care achieved through strong working relationships among providers.

We know the goal is to reform the Medicare delivery system so that patient-centered care is enhanced (as demonstrated by achievement of agreed-upon outcome measures) while the cost of delivering that care is reduced. Presumably, primary care providers will be at the helm of this new system, and fee-for-service payments will be replaced by outcome-based reimbursement. If that much of the vision is clear, the new rules should so state so that innovative approaches to care delivery and shared incentives can be developed, including an array of ACO models. In addition, the rules should provide some interim incentives to prod that innovation in a somewhat protected environment, just as the meaningful use rules provide carrots and sticks to prod EHR deployment.

II. Operational Issues

We offer comment on the following operational issues: (a) beneficiary assignment; (b) quality performance measures; (c) calculation of cost savings; (d) ACO membership; (e) alternatives for rural providers; and (f) ACO legal structures.

A. Beneficiary Assignment

Section 1899(c) directs the Secretary to develop an "appropriate method to assign Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services . . . ." A beneficiary, therefore, should be assigned to the ACO in which his or her primary care provider participates. No beneficiary should be assigned to an ACO without his or her knowledge and consent; to provide otherwise invites greater public distrust of health care reform.

Instead, CMS should assign a beneficiary to a particular ACO based on that ACO member-physician's representation that the individual has elected the physician's practice as his or her medical home. A beneficiary should be exclusive to one ACO at a time, with the ability to move between ACOs. (By contrast, there is no reason a provider cannot participate in more than one ACO, and such competition would likely foster greater cost savings and innovation.)

Several organizations, such as the Accreditation Association for Ambulatory Health Care, are developing programs that recognize and/or accredit providers as patient-centered medical homes based on specified standards. Initially, CMS should promulgate minimum medical home standards (*e.g.*, meaningful use of an EHR, basic case management services) for ACO participation, consistent with the "patient centeredness" requirement in Section 1899(b)(2)(H). These standards should incorporate criteria for patient election of a physician practice as his or her medical home provider, patient relocation to another medical home, and "eviction" (*i.e.*, when a physician may terminate a patient's election).

Unfortunately, MSSP is not likely to be a sufficient incentive for a physician to assume responsibility for case management. Under the current system, the physician receives no payment for providing these critical services. Thus, this work is left undone, to the detriment of the beneficiary and the payer. We urge CMS to provide some level of reimbursement to physicians for case management services furnished to beneficiaries who have elected ACOs. We believe the Secretary has the authority under Section 1899(i)(3) to include these payments as part of the MSSP; case management services clearly would "improve the quality and efficiency of items and services furnished under" Medicare Parts A and B.

B. Quality Standards

Section 1899(b)(3) requires the Secretary to identify quality standards by which an ACO's performance is to be measured. We urge CMS in developing the National Quality Strategy to focus on the need for consistency across programs with respect to performance measurement. To the fullest extent possible, the standards adopted for the MSSP should be the same measures on which hospitals and physicians are required to report for other programs, and those standards should be incorporated into the Stage 2 meaningful use requirements.

C. Benchmark for Measuring Cost Savings

Section 1899(d)(1)(B)(ii) directs the Secretary to establish a benchmark "using the most recent available 3 years of per-beneficiary expenditures for Parts A and B services for Medicare fee-

for-service beneficiaries assigned to the ACO. Such benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate." Rather than re-inventing the wheel, CMS should use the formula for calculating the base payment for a Medicare Advantage enrollee (base rate for enrollee's county of residence multiplied by the CMS-HCC weight) as the starting point for such benchmark. Establishing an ACO's benchmark based on the actual cost associated with those beneficiaries assigned to that ACO would be a disincentive for participation for those providers who already have implemented efficiencies to reduce cost, such as successful implementation of an EHR.

D. Eligible ACO Participants

Section 1899(b)(1) identifies the groups of providers of services and suppliers that are eligible to participate in the MSSP. These include physicians and non-physician practitioners ("ACO professionals") in group practice arrangements, networks of individual practices of ACO professionals, partnerships or joint venture arrangements between PPS hospitals and ACO professionals, PPS hospitals employing ACO professionals, and such other groups of providers and suppliers as the Secretary determines appropriate.

We have struggled to identify any reason CMS would want to limit the types of providers who can participate in an ACO, so long as they are qualified to receive Medicare payments. CMS should be encouraging development of broad care continuums, not limiting participation to PPS hospitals and physicians in certain practice settings. The manner in which beneficiaries are assigned to an ACO will ensure adequate participation by primary care providers. Otherwise, CMS should leave it to providers to determine who they want at the table to achieve the greatest cost savings while ensuring high quality care.

E. Rural Alternative

In general, rural providers care for more challenging patients than their urban counterparts. Residents of rural communities tend to be less active, more obese, and have higher rates of smoking and alcohol use, all of which are "trip wires" for chronic diseases such as diabetes, hypertension, and coronary artery disease. Rural providers must meet these challenges with a inadequate array of health care resources such as specialists, skilled staff, facilities, and equipment. Historically, geography and politics have prevented providers from collaborating to leverage their resources to provide better quality and a broader range of services within a region.

With some modification, the MSSP could provide strong incentives for providers within a region to build collaborative care networks. First, given the lack of population density, it would be

extremely difficult for a rural ACO to meet the 5,000 beneficiary threshold. For some areas in Kansas, for example, the geographic reach of an ACO would have to spread over an area larger than most states in the Northeast. Second, given historic challenges, it would be challenging for rural providers to integrate all levels of care. Instead, a more focused approach would provide opportunities to build trusting relationships.

We propose an alternative for rural networks that assume accountability for patients within the region suffering from a particular chronic disease. All other requirements for the MSSP would be applicable to those rural ACOs ("RACOs"), including governance structure, the method by which patients elect to participate, quality standards, and the calculation and payment of cost savings.

Our experience has taught us that forming rural networks is challenging, given the need to overcome historical distrust and providers' lack of resources and sophistication. To flourish, these networks require seed money and technical support. We urge CMS to provide grants or loans against future savings to providers within a region that demonstrate a commitment to forming a rural health network. Also, CMS should provide on-the-ground technical support, similar to the Regional Extension Program support for primary care physicians' EHR adoption.

F. ACO Legal Structure

We assume that the proposed regulations will clarify a number of ambiguities in the law regarding the legal structure of ACOs. In doing so, however, we encourage CMS to define the legal structure parameters broadly to allow for innovation and flexibility in structuring unique configurations of providers and complying with diverse state laws.

One needed clarification relates to the requirement that the ACO have the ability to receive and distribute payment. We believe that the regulations should acknowledge that this could be accomplished in a variety of ways. For example, an ACO could be a contractual joint venture with one of the joint venturers being tasked to handle the mechanics of receipt and distribution of funds in accordance with the joint venture agreement. Or, an ACO could be a wholly owned subsidiary (*e.g.*, an LLC or non-profit corporation) of a hospital or physician group that has a "mechanism for shared governance" that provides for governance participation by the other non-owner ACO participants. Flexibility in this regard will be critical to allow not-for-profit providers and for-profit providers to form ACOs and to assure that federal tax-exempt status and state laws (such as fee-spitting and corporate practice of medicine prohibitions) do not create barriers to ACO formation.

III. WAIVER AUTHORITY

In contemplating and drafting the regulations to implement the MSSP, we urge CMS to keep a fundamental premise in mind: *In pursuit of shared savings, the competition among providers will be for beneficiaries, not referrals.* If providers are truly seeking shared savings, the safeguards against Medicare fraud change from anti-referral and CMP laws to quality measures and cost savings requirements. This allows the Secretary to waive the anti-referral and CMP laws, so long as quality is maintained and costs are reduced. Quality measures will protect beneficiaries from stinting, and cost savings requirements will protect the Medicare program from fraud and abuse.

The Secretary should: (1) create broad waivers of the anti-referral and CMP laws to encourage ACO development; and (2) require demonstrated quality and cost savings to protect Medicare from abuse.

A. Breadth of Waivers

Broad waivers are necessary to give potential ACO participants sufficient comfort to make the investment of time, effort, and money necessary to form and implement ACOs. The waivers should extend to: formation activities, implementation, and relationships among providers within the ACO. For example, a hospital should be permitted to share its savings with ACO member physicians (what is now referred to as gain-sharing) so long as quality standards are satisfied.

The waivers should also extend to protect private ACO activities. Although, at first blush, it would seem that CMS regulations would not impact non-Medicare payers' use of ACO structures, it is important for CMS to clarify that it will not challenge non-Medicare payers' use of ACO structures as an offer of remuneration to induce primary care physicians to refer beneficiaries to an ACO. The following example illustrates this issue:

> ACO #1 is Medicare approved and participates in the MSSP. ACO #1 has also negotiated three contracts with private payers (Payers A, B, and C) to use the same or similar method of sharing savings with the ACO participants.
>
> ACO #2 is Medicare approved and participates in the MSSP but has no other similar arrangements with private payers.
>
> Primary Care Group is an independent practice with 20 physicians. It has 2,500 fee-for-service Medicare beneficiaries and 4,000 private pay patients, 2,000 of which are covered by Payers A, B, and C. Both ACOs approach Primary Care Group to join their

respective ACOs. Primary Care Group decides to join ACO #1 because it offers the ability to receive shared savings payments for an additional 2,000 private pay patients.

The Secretary's waiver must protect ACO #1 and Primary Care Group from allegations that ACO #1 has offered/paid remuneration (private pay shared savings) to induce Primary Care Group to "refer" its Medicare fee-for-service beneficiaries to ACO participants.

B. Process for Obtaining a Waiver

To give potential participants sufficient assurance to form and participate in ACOs and, at the same time, protect beneficiaries and the Medicare program from abuse, we recommend a process substantially as follows:

1. ACO participants would file an ACO application (similar to a provider application or a 501(c)(3) (Form 1023) application). This would include information and documentation supporting compliance with basic ACO requirements such as:

- the legal structure
- the governance structure
- sufficient provider panel
- number of beneficiaries
- patient-centeredness
- cost benchmarks
- quality measures
- EHR capability
- methods of reporting
- process for promoting evidence-based medicine and coordinating care

2. Upon submission of a complete application, the HHS waiver (AKS, Stark, and CMP) would attach to all aspects of the ACO, the relationships among ACO participants, and the ACO's formation and implementation.

3. To retain waived status, the ACO must: (a) achieve accreditation (assuming such a process exists) or comply with annual accountability reporting standards within a specified time period (*e.g.*, one year); and (b) achieve cost savings within a specified time period (*e.g.*, two to three years).

4. Failure to meet accreditation/reporting or cost-saving standards would result in a probationary status (*e.g.*, for one year).

5. Continued failure to meet such standards after the probation expires would result in loss of the waiver and require that the ACO wind down, dissolve the arrangement, and repay the shared savings, if any.

We thank you for the opportunity to submit these supplemental comments, and we look forward to reviewing the proposed regulations regarding the MSSP.

Very truly yours,

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