

June 6, 2011

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

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

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

Dear Dr. Berwick:

On behalf of the Catholic Health Association of the United States (CHA), the national leadership organization of more than 2,000 Catholic health care sponsors, systems, hospitals, long-term care facilities, and related organizations, I welcome the opportunity to submit comments regarding the proposed rule published on April 7, 2011 implementing the Medicare Shared Savings Program (MSSP), as specified in section 3022 of the Affordable Care Act (ACA). Under the proposed rule, accountable care organizations (ACOs) meeting certain requirements would be eligible to share savings or losses with the Medicare program.

CHA and its members are committed to transforming the U.S. health care system so that it will serve patients better and more efficiently. As a central component of our vision for health care, we believe that health care should be patient-centered, addressing health needs at all stages of life through services that are coordinated and integrated all along the continuum of care, with accountability for health outcomes. We also call for safe, effective health care delivered with the highest possible quality to achieve the best outcomes for patients.

CHA believes ACOs offer a promising opportunity to achieve those goals, through improved integration of inpatient and outpatient care and joint accountability for care delivery across providers and over time. We appreciate the thoughtfulness and hard work that went into developing CMS' proposal. Leading the way in a fundamental rethinking of how health care is delivered in our country is a daunting enterprise, and will be an evolutionary process. Many of CHA's members have made great strides in implementing various models of integrated care, and have been enthusiastic about the opportunity to participate in MSSP ACOs.

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It is in a spirit of working together to achieve a new vision of health care that we offer these comments. We suggest that CMS reconsider or further develop its approach to several key design elements in the proposal. Many organizations are reconsidering their initial interest in the program, but with the right adjustments in design, we believe more health care providers would participate and the ACO concept can live up to its full potential for improving the quality of care and reducing Medicare health care expenditures.

Eligibility and Governance

The proposed rule specifies the criteria that an ACO must meet in order to participate in the MSSP. For example, there are detailed requirements about clinical management and oversight and the structure and composition of an ACO's governing body; stringent standards for electronic health records (EHRs)(at least 50% of primary care physicians must be meaningful users by the beginning of the second year); and eight detailed criteria in order to meet the patient-centeredness requirement.

CHA is concerned that the MSSP could be stymied by overly ambitious and overly prescriptive requirements, especially in the early years of the program. While the general capabilities and functionalities identified in the proposed rule certainly appear relevant to ACO performance and success, we believe that CMS should not expect an ACO to demonstrate all of these capabilities and functionalities from the very beginning of the program. Instead, we believe that CMS should ask applicants to indicate how they plan to meet each applicable requirement over the course of their 3-year agreement with Medicare. CMS has already signaled that this approach would be acceptable for some requirements. For example, in the proposed rule, with respect to patient-centeredness, CMS says that an ACO would be expected to have a process in place or clear path to develop such a process to electronically exchange summary of care information when patients transition to another provider or setting of care, both within and outside the ACO. CHA believes that similar "clear path" options should be accorded to ACOs for other criteria and requirements. This would allow ACOs to focus on certain capabilities at the beginning of the program and phase in other capabilities later during the agreement period.

CHA also believes that CMS should, to the greatest extent possible, take a non-prescriptive approach to ACO capabilities and functionalities (that is, indicate which capabilities are important but minimize demands on how such capabilities are to be accomplished or demonstrated). This approach will not only provide necessary flexibility for new ACO ventures but also allow for an element of creativity and experimentation. This would be better than attempting to identify a "one size fits all" approach for meeting patient and community needs at the very beginning of the MSSP.

For example, CHA strongly supports EHRs, but we believe that it is premature to demand some specific EHR meaningful use level of performance—for primary care physicians, all health professionals or hospitals—as part of the ACO regulation. CMS is already providing payment

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incentives for EHR meaningful use and providers are aware that penalties for failure to become EHR meaningful users loom. This should be sufficient for the time being rather than attempting to impose additional requirements on ACOs.

CHA also strongly supports the inclusion of patient-centeredness in the MSSP, and appreciates the attention given this topic by CMS. While the proposed patient-centered criteria are generally appropriate, prospective ACO applicants may be at different stages in setting up these capabilities and taking varying approaches, given the patients they serve, their existing capabilities and those of their partners. The proposed retrospective beneficiary assignment means an ACO will not be able to identify all its respective beneficiaries and may not be able to meet criteria such as individualized care plans for all beneficiaries in the ACO. We believe CMS should allow applicants to explain how they plan to address these criteria over the course of the contract, rather than to demonstrate immediate capacity to implement all eight.

It is essential to ensure that beneficiaries receive accurate, complete and timely information on ACOs from both the ACO and CMS. However CHA asks CMS to reconsider the requirement that all "marketing materials and activities" be preapproved by CMS before being communicated to beneficiaries. The term as defined in the proposed rule includes not just marketing materials but a whole range of types of communication with beneficiaries. We are concerned that this requirement for preapproval could cause unnecessary delays, and suggest that CMS consider other options, such as developing standard forms and language to be used by ACOs in the areas of most concern; limiting the types of documents that require preapproval; or allowing ACOs to use the materials pending approval, particularly if a period of time such as 30 or 45 days has passed since submission to CMS for review.

The ACA specified four groups of providers and suppliers capable of forming an ACO on their own: ACO professionals in group practice arrangements; (2) networks of individual practices of ACO professionals; (3) partnerships or joint venture arrangements between hospitals and ACO professionals; and (4) hospitals employing ACO professionals.

CHA believes the most successful ACOs over the longer term, those with sustainable and credible savings, are likely to be those that include a broad array of providers and suppliers, including one or more hospitals, where joint action to increase quality and reduce unnecessary expenditures is possible. Including hospitals in an ACO would enhance the collaboration with physicians necessary to ensure that Medicare beneficiaries receive optimal care, the goal of the ACO program. Hospitals are the entities most likely to have the infrastructure, staff, capital access and other resources essential for successful ACOs, and have direct control over a large proportion of Medicare spending. Indeed, there is some concern that an ACO that excludes hospitals could achieve savings by significantly reducing beneficiary use of hospital services without sharing the savings with the hospital(s), possibly compromising the ability of such hospital(s) to serve the local community.

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We urge you to consider ways to encourage the inclusion of hospitals in ACOs. We are pleased that CMS proposes to add Critical Access Hospitals that utilize method II billing to the list of entities able to form an ACO. CMS should also consider recognizing ACOs formed by hospitals and affiliated ACO professionals, who are neither employed by or in joint ventures or partnerships with the hospital. This would also address ACO formation issues in states with corporate practice of medicine and in areas where most physician practices are small group practices.

Similarly, ACOs offer great promise in allowing physicians and hospitals to coordinate care and accept joint accountability with post-acute care facilities, home health agencies and other health providers and professionals.

CMS could also consider asking ACO applicants to demonstrate that they have considered the likely impact on their assigned Medicare beneficiaries, and their communities as a whole, as a result of the inclusion or exclusion of certain types of providers.

Establishing the 3-Year Agreement with the Secretary

To help ACOs accomplish the goals of the MSSP, CMS proposes to share three separate types of data with them. Two of the three types of data focus on beneficiaries who would historically have been assigned to an ACO (had it existed as such). Under the third type of proposed data sharing, CMS would allow ACOs to request, on a monthly basis, certain beneficiary identifiable information for beneficiaries who have thus far received a primary care service from one or more of four primary care physician types participating in the ACO (family practice, general practice, internal medicine and geriatrics). We recognize that CMS' offer of data sharing is intended to respond to a general consensus that beneficiary assignment to ACOs should be prospective in nature, rather than retrospective as proposed by CMS.

As noted below, CHA continues to believe that prospective assignment of Medicare beneficiaries to ACOs would be preferable. However, if this policy is not changed, we believe that the proposed data sharing could be made more useful to ACOs if it included a process under which they would periodically receive the name, date of birth, sex and Health Insurance Claim (HIC) number for each beneficiary who would be assigned to the ACO if such assignment was made based on all information available to CMS as of a date certain. This might, for example, be done on a quarterly basis. In other words, the ACO would not only periodically receive beneficiary specific information for those beneficiaries who have, to date, received one or more primary care services from the ACO's primary care physicians (as proposed), but the ACO would also periodically be informed about the specific beneficiaries who appear on track to be assigned to the ACO in the final analysis.

Assignment of Medicare Fee-For-Service Beneficiaries

As noted above, CMS proposes to assign Medicare beneficiaries to an ACO retrospectively (that is at the end of each performance period) based on their utilization of certain primary care

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services. CHA believes that prospective assignment of beneficiaries is a better approach. If ACOs know who their assigned beneficiaries are they will have more accurate information on the health needs of the population for which they are being held responsible, and will be better able to design appropriate care coordination and management strategies to meet those needs. On the other hand, assigning beneficiaries retrospectively will impose operational challenges on ACOs and make it difficult for them to focus on what is truly important. Retrospective assignment may even cause some organizations to shy away from applying to become ACOs in the first place because they may conclude that the risks and uncertainties are simply too great. This will be especially true if the beneficiary assignment methodology ends up assigning some beneficiaries who have had minimal contact with an ACO's providers and suppliers during the preceding year (which could be as little as a single visit). In sum, CHA asks that CMS reconsider its plan to retrospectively assign Medicare beneficiaries to ACOs.

The proposed rule also notes CMS' plan to develop standardized written materials for beneficiaries, which would be used to provide written notice to beneficiaries about a provider's or supplier's participation in the MSSP and the potential for CMS to share beneficiary identifiable data with ACOs when a beneficiary receives services from a physician on whom assignment to the ACO is based. CMS proposes to allow beneficiaries to opt-out of having their data shared with the ACO. ACOs are to provide to each beneficiary as part of their office visit with a primary care physician a form containing a phone number, fax number or e-mail address for beneficiaries to contact and request that their data not be shared. This opt-out option would not affect a beneficiary's ability to continue to receive services from an ACO's participating providers and suppliers, including its primary care physicians, nor would it necessarily prevent a beneficiary from being assigned to that ACO.

CHA urges CMS either to amend its proposed opt-out option or to delete it in the final rule. We believe that beneficiaries who do not wish to allow their data to be shared should be able to withdraw fully from the ACO structure, while continuing to see their doctor or other providers who are in the ACO. This would also avoid the situation of denying to the ACO information that it needs to fully coordinate and manage care for its assigned beneficiaries. We are also concerned the current proposal could cause unnecessary confusion for beneficiaries, who may choose to disallow data sharing and then not understand why they are still in the ACO, or who, on the other hand, may conclude that exercising the opt-out option means they can no longer receive care from their customary physician. We note, too, that CMS did not propose a beneficiary opt-out option in the case of beneficiary information (name, date of birth, gender, and HIC number) provided to ACOs that is based on claims data from the three-year benchmark period. In sum, CHA believes that the proposed opt-out option should be amended or dropped. We note here also how important it is that CMS develop beneficiary educational materials that paint a balanced picture of the potential benefits and potential risks associated with the ACO model.

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Quality and Other Reporting Requirements

CMS proposes to use 65 performance measures in five domains in year one of the ACO program. Further, it appears that an ACO would ultimately need to exceed the minimum attainment level for all applicable measures in order to be eligible for shared savings. However, in year one, ACOs would be required to report full and accurate data for all measures, but not meet any specific performance target.

CHA urges CMS to reduce the number of performance measures that ACOs are required to meet (or report data for) in the early years of the program. We note that CMS used a much smaller set of performance measures under the Medicare Physician Group Practice (PGP) demonstration project (a maximum of 32 measures), and even chose to phase in this measure set over time. We believe that a similar approach should apply to the ACO program. We also believe that it would be unreasonable to require an ACO to exceed the minimum attainment level for all applicable measures, rather than some minimum score across all measures and measure domains. CMS may well not be intending to require ACOs to exceed the minimum attainment level for all measures in order to qualify for shared savings; readers of the proposed rule have drawn different conclusions about CMS' intentions in this regard. In any event, one option would be for CMS to adopt fewer performance measures and to require ACOs to achieve a minimum score across all these measures in order to qualify for shared savings.

Shared Savings Determination

We appreciate that the proposed rule includes two possible models for ACOs to pursue. However, under both options an ACO would be at risk for shared losses. Under the one-sided model, this risk would exist for year three, while under the two-sided model it would exist for all three years of the agreement. CHA urges CMS to provide an ACO model that involves only the potential for shared savings, never shared losses, at least for the early years of the program. This model could substitute for what is now described as the one-sided model or serve as yet another option under the MSSP. We believe this would allow a wider range of interested organizations to participate in the MSSP without fear of incurring shared losses during their first, three-year agreement with Medicare. In addition, this approach strikes us as most consistent with Congressional expectations for the MSSP. Further, given all the uncertainties surrounding key ACO design elements, including the formulae for determining shared savings and shared losses, we believe that a "shared savings only" model is needed is get the MSSP off the ground.

In calculating both the benchmark and actual ACO expenditures (for purposes of determining shared savings and shared losses), CMS proposes to make almost no adjustments. For example, CMS proposes not to adjust either ACO benchmarks or ACO actual expenditures for payments to hospitals for direct graduate medical education (GME), indirect medical education (IME), or disproportionate share hospital status (DSH). Similarly, no adjustment is proposed to reflect bonus payments made to hospitals under the new value-based purchasing policy, incentive payments made to hospitals for meaningful use of EHRs, or special payments made to primary

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care physicians under a provision of the ACA. Failure to make adjustments in these cases would essentially penalize the affected ACOs. In effect, hospitals would be receiving mixed messages; if they do what is necessary to qualify for incentive or bonus payments, their ability to produce shared savings will be compromised, at least to some extent, and their risk of incurring shared losses is likely to increase. Failing to adjust for DSH, IME and GME could create a significant disincentive for an ACO to include hospitals that receive such payments. It would be unfortunate if the program design operated to unintentionally keep these hospitals from participating in ACOs.

With respect to adjustments to the ACO benchmarks and/or actual spending, CMS argues that it does not have sufficient statutory authority. CHA disagrees. First, section 1899(d)(1)(B)(ii) explicitly gives the Secretary the authority to adjust ACO benchmarks for "such other factors as the Secretary determines appropriate." Since many, most or perhaps even all adjustments to the benchmarks would require commensurate adjustments to actual ACO expenditures in order to permit "apples to apples" comparisons for purposes of shared savings or shared loss calculations, we believe the Secretary was at least implicitly given authority to make such adjustments to actual ACO expenditures. Perhaps more importantly, section 1899(i) essentially authorizes "any [ACO] payment model that the Secretary determines will improve the quality and efficiency of items and services furnished under [Medicare]" [emphasis added]. In the proposed rule, CMS itself acknowledges that section 1899(i) provides very broad authority, even the authority to sidestep other explicit statutory requirements. For example, although section 1899(d)(1)(B)(ii) states that the ACO benchmark shall be "updated by the projected absolute amount of growth in national per capita expenditures" [emphasis added], CMS argues that the authority provided by section 1899(i) would nonetheless permit CMS to adopt an "alternative" under which the ACO benchmark would be updated by "the lower of the national projected absolute amount of growth in national per capita expenditures or the local/State projected absolute amount of growth in per capita expenditures" [emphases added]. In sum, CHA believes that the ACA provides sufficient authority for CMS to make important adjustments to the ACO benchmarks and actual ACO expenditures.

Further, in determining ACO benchmarks, CMS proposes not to adjust for changes in the assigned beneficiary population risk score during the ACO's performance year (that is, changes in risk score relative to the risk score that is based on data from the three-year, historic benchmark period). CHA urges CMS to reconsider. While we appreciate CMS' concerns about the implications of coding improvements over time, we believe that refusing to make <u>any</u> ongoing adjustments for changes in risk score goes too far and could significantly disadvantage organizations participating in the MSSP. Instead of refusing to adjust for changes in risk score, CMS could, for example, monitor changes in risk scores, both for beneficiaries assigned to ACOs and those not so assigned, and use this information to cap allowed changes in ACO risk score. Thus, an ACO's risk score could be adjusted over time but not allowed to change at a rate greater than changes in risk score for a comparator beneficiary population at the local, regional or national level.

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Under the proposed rule, the maximum sharing rate would be 52.5 percent under the one-sided model and 65 percent under the two-sided model. CHA believes that the maximum sharing rates proposed by CMS are much too low. They are obviously much lower than the 80-20 shared savings formula used under the PGP demonstration. Low maximum sharing rates will only serve to discourage participation in the MSSP and fail to provide adequate and timely compensation to ACOs for their up-front and ongoing operational costs. Higher maximum sharing rates will be especially important at the beginning of the MSSP when ACOs face the greatest uncertainty. CMS also proposes a minimum savings rate, a threshold of savings which must be met before the ACO is eligible for sharing savings. We believe that all ACOs that surpass their minimum savings rate be allowed to share in "first dollar savings," not just those in a shared risk model. Once an ACO demonstrates it has achieved adequate savings in which to share, the sharing rate should apply to all savings achieved. Taking this more balanced approach would make more savings available to ACOs, helping to offset start up costs and making the program more attractive.

The proposal states that a flat 25 percent withholding rate would be applied annually to an ACO's earned performance payment, under both the one-sided and two-sided ACO models. This is presumably done to provide a means to offset future losses, and CHA acknowledges that such a withhold policy was applied to the Medicare PGP demonstration. However, the proposed rule also would require an ACO to establish a self-executing method for repaying losses to the Medicare program by, for example, obtaining reinsurance; placing funds in escrow; obtaining a surety bond; establishing a line of credit as evidenced by a letter of credit that the Medicare program could draw upon; indicating that funds may be recouped from Medicare payments to the ACO's participants; or establishing another repayment mechanism. CHA urges CMS to drop the proposed withhold policy so that all earned shared savings may be paid as promptly as possible to affected ACOs. As CMS itself acknowledges, there will be significant up-front costs involved in developing an ACO and in applying to participate in the MSSP, and significant ongoing costs as well. Withholding earned savings from ACOs limits their ability to cover these up-front and ongoing costs, and the withhold policy is likely to discourage ACO applications. Further, CHA believes that the separate requirement for a self-executing mechanism to cover any shared losses that might be incurred by an ACO makes the withhold policy redundant and unnecessary.

Lastly, we take this opportunity to observe that under the ACA and the proposed rule, an ACO's benchmark would be re-based at the beginning of each new agreement period (with the first such re-basing occurring after an ACO's first, three-year agreement with Medicare, assuming that the ACO wishes to renew the agreement). Over the longer term, this benchmark re-basing is likely to mean that an ACO will find it increasingly difficult to produce shared savings, especially if the ACO's participants were relatively efficient to begin with. For example, savings achieved through changes in patient management or improvements in quality will, over time, be reflected in re-based benchmarks, meaning that an ACO would need to find new ways to produce additional savings. For many ACOs, this could lead to the problem of diminishing returns. In fact, unless this issue is addressed, we believe that the long-term viability of the ACO concept may be called into question. Worse yet, ACOs in the MSSP could find themselves subject to

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increasingly unreasonable expectations or even heightened pressures to skimp on patient care merely to meet savings targets.

We hope the preceding comments are helpful. If you have any questions about these comments or need more information, please do not hesitate to contact me or Kathy Curran, Senior Director Public Policy, at 202-721-6300.

Sincerely,

Michael Rodgers

Senior Vice President

Public Policy and Advocacy