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June 2, 2011

BY ELECTRONIC DELIVERY

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

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

Dear Dr. Berwick:

The Association of Community Cancer Centers (ACCC) thanks the Centers for Medicare & Medicaid Services (CMS) for this opportunity to comment on the Medicare Shared Savings Program: Accountable Care Organizations Proposed Rule (the "Proposed Rule") regarding Accountable Care Organizations (ACOs) and the Medicare Shared Savings Program (MSSP).¹

ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 900 member institutions and organizations, when combined with our physician membership, treat 60 percent of all U.S. cancer patients.

ACCC applauds CMS's aim to create better health for individuals, better health for populations and lower growth in

¹ 76 Fed. Reg. 19528 (April 7, 2011).

expenditures through this program. Although the MSSP, as proposed by CMS, is focused on primary care, ACCC believes that community cancer centers can play a vital role in helping ACOs achieve these aims. With this in mind, we encourage CMS to:

1. Protect beneficiary access to cancer care by requiring ACOs include specialists in their leadership and management structures and by establishing additional protections for access to specialty care and clinical trials;
2. Consider the creation of oncology-centered ACOs under the Center for Medicare and Medicaid Innovation (CMMI);
3. Reduce barriers to community cancer centers' participation in ACOs by creating an option to participate under the one-sided risk model for all three years;
4. Employ a local growth rate trending factor for setting benchmarks to provide an attainable standard for all ACOs without discouraging participation;
5. Adopt a net sharing rate for savings starting at all savings above the Minimum Savings Rate (MSR);
6. Set higher upper-performance payment limits for shared savings to encourage participation;
7. Encourage future development of life-saving cancer treatments by accounting for significant initial costs of such therapies;
8. Develop a system to better account for beneficiaries that do not receive all of their care from one ACO;
9. Work with entities already engaged in cost-saving activities to ensure that they can participate in the MSSP or similar programs; and
10. Not withhold half of the shared savings in order to ensure that funds will be available for risk-sharing.

We discuss these recommendations more fully below.

I. CMS should protect beneficiary access to cancer care in the MSSP by requiring ACOs include specialists in their leadership and management structures and by establishing additional protections for access to specialty care and clinical trials.

The Affordable Care Act (ACA) requires that assignment of beneficiaries to ACOs be determined based on primary care services provided by ACO professionals who are physicians.² CMS proposes to implement this provision by assigning beneficiaries based on primary care services received from a predefined group of primary care providers, which CMS proposes would include physicians with a

² Social Security Act (SSA) § 1899(c).

designation of internal medicine, geriatric medicine, family practice, and general practice.³ Unlike the designated primary care physicians, specialists would be permitted to participate in multiple ACOs and the primary care services they provide would not be used to assign beneficiaries to ACOs. We understand that under CMS's intended interpretation of the Proposed Rule, a beneficiary could be assigned to an ACO if he or she received only one primary care service from a primary care provider who participates in an ACO. This approach would allow many beneficiaries being treated for cancer to be assigned to ACOs, even though they received most of their care in the relevant period from specialists.

CMS based this proposal, in part, on its goals of protecting access to specialists, particularly in areas of the country that might not have many specialists, and ensuring competition among ACOs.⁴ We appreciate these concerns about protecting access to care from appropriate specialists, but we believe that additional measures will be needed if CMS implements this method of assigning beneficiaries to ACOs.

First, we urge CMS to require that ACOs include specialists in their leadership and management structure. CMS correctly recognizes that oncologists and other specialists "are often the principal primary care" providers for certain beneficiaries.⁵ These specialists' expertise will be essential to the ACO as it works to comply with the proposed requirement that it "develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the goals of better care for individuals, better health for populations, lower growth in expenditures."⁶ Because ACO participants would be required to comply with these guidelines and processes,⁷ it is essential that the physicians who are most knowledgeable about the conditions being treated are involved in developing and implementing them. Indeed, we do not see how an ACO can simultaneously improve care and reduce the rate of growth of its expenditures without the input of the relevant specialists. ACOs can develop and implement appropriate guidelines and processes only if specialists are included in the ACOs' leadership and management structures.

Second, CMS should develop quality measures to encourage ACOs to ensure that beneficiaries receive appropriate cancer care. CMS proposes to include several quality measures on use of cancer screening services in the MSSP,⁸ but does not

³ 76 Fed. Reg. at 19565.

⁴ Id.

⁵ Id. at 19564.

⁶ Id. at 19543.

⁷ Id.

⁸ Id. at 19579.

include any measures on treatment of cancer. We support inclusion of the screening measures because they will help to promote appropriate detection of breast and colorectal cancer, but they are not sufficient to protect and promote quality cancer care by ACOs. CMS should include some of the consensus-based, endorsed quality measures on cancer care that are used in Medicare's other quality programs to align quality measurement across these programs.

CMS also should develop measures to encourage timely referrals to specialists. This is particularly important in oncology, where the success of a patient's treatment, and the cost of the course of treatment, can depend on how quickly care is provided after the cancer is diagnosed. Appropriate and timely referrals to oncologists and other specialists will be needed to ensure that beneficiaries' cancers are diagnosed and treated early, when the required care would be less costly and the beneficiary has the best chance of successful treatment. CMS should work with stakeholders and the National Quality Forum (NQF) to develop measures that will measure the timeliness of referrals to oncologists and other specialists.

Third, CMS should encourage ACOs to participate in clinical trials. Clinical trials provide excellent opportunities for some beneficiaries to receive cutting-edge care while helping to improve the standard of care for all patients. This is especially true in oncology, where many of the advances in care involve discovery of new uses for existing therapies, as well as development of new therapies. For beneficiaries fighting cancer, the most appropriate care may be provided in a clinical trial, and ACOs should be encouraged to protect access to specialty care available in the research setting. CMS could achieve this goal by awarding "bonus points" to ACOs, similar to the incentives offered to Federally Qualified Health Centers and Rural Health Centers, based on their participation in clinical trials. Alternatively, quality measures should be developed to encourage clinical trial participation.

II. CMS should consider the creation of oncology-centered ACOs under the authority of the CMMI.

CMS's proposed method of assignment could result in some cancer patients not being assigned to an ACO because they receive all of their primary care from their oncologists. To allow these beneficiaries the opportunity to participate in an ACO and to test the use of ACOs for cancer care, we recommend that CMS consider the creation of oncology-centered ACOs under the authority of the CMMI. Patients would be assigned to these ACOs based on the care they receive from specialists who most often are involved in treating cancer, including oncologists, hematologists, radiation oncologists, and radiologists. CMS could test new payment models for

these ACOs that would encourage better coordination of care for beneficiaries being treated for cancer. We would be happy to meet with CMS to discuss this idea.

III. CMS should reduce barriers to community cancer centers' participation in ACOs by creating an option to participate under the one-sided risk model for all three years.

Considering the need to invest in implementation of electronic health records (EHR), revise corporate governance structures, and comply with legal requirements, there will be significant startup costs in order to participate in an ACO. CMS estimates average start-up costs and first year operating expenses will reach \$1.7 million for each ACO. ACCC believes this amount likely will be even higher and will prove to be a significant barrier to entry for many small or rural hospitals and providers. The American Hospital Association (AHA) estimates initial start-up costs to be substantially higher, between \$11.6 and \$26.1 million, in a recent study.⁹ Given these considerable initial costs, as well as uncertainty regarding how the program will work, oncology providers are concerned that CMS's proposal to require all ACOs to accept downside risk at some point during the initial three-year agreement period will discourage many community providers from participating. To ensure that such providers have the opportunity to participate in the program, ACCC believes that it is important to allow ACOs to participate under the one-sided risk model for an initial three-year agreement period. After an initial three-year agreement period, ACO participants would have the experience necessary to determine whether continued participation in the MSSP is feasible and what changes would be necessary in order for them to be more effective. With such experience, and the chance to have absorbed some of the initial operational costs, requiring ACOs to participate in more aggressive risk-benefit models would be appropriate only after the initial three-year period.

IV. CMS should employ a local growth rate trending factor for setting benchmarks to provide an attainable standard for all ACOs without discouraging participation.

In establishing benchmarks for the MSSP, CMS must establish the "benchmark for each agreement period 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."¹⁰ CMS must trend the per capita costs for each year in the benchmark forward to benchmark year three and has proposed to do so

⁹ American Hospital Association, *New Study Finds the Start Up Costs of Establishing an ACO to be Significant*, available at <http://www.aha.org/aha/press-release/2011/110513-pr-aco.html>.

¹⁰ 76 Fed. Reg. at 19603.

using a national growth rate.¹¹ Although ACCC agrees with CMS that use of a growth rate, as opposed to a flat dollar amount equivalent to the absolute amount of growth in per capita expenditures is appropriate, we believe that the use of a local, as opposed to national, growth rate would more appropriately reflect the different experiences ACOs will face based on geographic location.

As noted in the Proposed Rule, a national growth factor could “disproportionately encourage the development of ACOs in areas with historical growth rates...that would benefit from having a relatively higher base, which increases the chances for shared savings, while relatively discouraging development of ACOs in areas with historically higher growth rates above the national average that would have a relatively lower base.”¹² ACCC believes benchmarking should reflect the experience of ACOs in different geographic settings and thereby encourage ACOs to participate nationwide, instead of only in certain pockets of the country. Therefore, we urge CMS to adopt a local growth rate to trend per capita expenditures included in the benchmark forward.

V. CMS should adopt a net sharing rate for savings starting at all savings above the Minimum Savings Rate (MSR).

With regard to ACOs participating in the one-sided model, CMS considered several options to determine the amount of savings such ACOs should be eligible to receive. CMS is proposing that once an ACO in the one-sided model surpasses the MSR, it would be eligible to share in savings only above a 2-percent threshold, calculated as 2 percent of the ACO’s benchmark.¹³ CMS believe that such a threshold is necessary to protect the program from “sharing unearned savings” and to help “ensure that shared savings are due to enhanced care coordination and quality of care on the part of the ACO.”¹⁴ ACCC believes that this requirement could be a significant deterrent to ACO participation. Although CMS has proposed to exclude certain ACOs from the savings threshold, and allow them to share in savings on a first dollar basis as can ACOs participating under the two-sided model, the uncertainty regarding how the MSSP will operate in its first few years counsels in favor of allowing all ACOs to be eligible for shared savings on a first dollar basis, at least initially. CMS has included numerous policies to ensure that shared savings are due to enhanced care coordination and quality of care that apply specifically to ACOs in the one-sided model (the sliding scale MSR) and the two-sided model (monitoring and reporting requirements). ACCC is confident that these protections are sufficient to accomplish the desired goal of improved efficiency

¹¹ Id. at 19610.

¹² Id.

¹³ Id. at 19613.

¹⁴ Id.

without unnecessarily deterring ACO participation, especially for smaller ACOs that might not meet one of CMS's specific exceptions.

VI. CMS should set higher upper-performance payment limits for shared savings to encourage participation.

ACCC also views the performance payment limits in the Proposed Rule as a deterrent for providers and suppliers to join an ACO. CMS is proposing upper performance payment limits of 7.5 percent for the first two years of participation in "Track 1", and a 10 percent upper limit for the third year and for ACOs participating in "Track 2".¹⁵ Considering the significant entrance costs and risk sharing associated with the MSSP, many oncology providers view the costs and risks too high, while the incentives too low to join an ACO as a participant. Therefore, ACCC recommends that CMS adopt appreciably higher upper limits to encourage ACO participation by community providers.

VII. CMS should encourage future development of life-saving cancer treatments by accounting for significant initial costs of such therapies.

ACCC is concerned about the effect the MSSP may have on the future development of innovative cancer treatments. As CMS recognizes, any risk-bearing arrangement increases the incentives to minimize costs and therefore decreases the incentive to avoid potentially high-cost treatments that may not have savings that are realized within the relevant time period for ACOs. ACCC believes that CMS should take into consideration the fact that the MSSP may discourage the use of, and therefore reduce the incentive to develop, new treatments that may improve outcomes for cancer patients and substantially reduce costs in the long run but may increase costs in the short turn. CMS may do so by providing additional mechanisms to ensure that access to state-of-the-art care and continued innovation are not hindered by the MSSP.

One such mechanism would be a carve-out from the benchmark and performance year expenditures for new technologies that are subject to special payment provisions elsewhere in Medicare. Under this approach, new technologies that are subject to payment provisions that protect access to innovative care under the Medicare hospital inpatient and outpatient prospective payment systems (PPS) also would be protected under the MSSP. In particular, drugs, biologicals, and devices that are granted pass-through status under the outpatient PPS or technologies that receive add-on payment under the inpatient PPS would be excluded from the MSSP calculations. This exclusion also should apply to these

¹⁵ Id. at 19616.

same products used in physician offices, even though the pass-through and inpatient add-on do not apply in the physician office setting. This mechanism would align Medicare incentives for appropriate use of new technologies under the fee-for-service and MSSP payment methodologies.

CMS also should reduce the outlier threshold from the 99th percentile to the 95th percentile to help ensure that ACOs are not penalized for using innovative technologies in the MSSP. We support CMS's proposal to truncate a beneficiary's expenditures to "minimize variation from catastrophically large claims,"¹⁶ but we think that the proposed use of the 99th percentile would set the bar too high. A lower threshold would provide greater protection against flawed analyses due to use of important new technologies by a few patients.

Finally, we recommend that CMS monitor ACOs for changes in beneficiary access to new technologies. CMS should compare access to new technologies for beneficiaries within ACOs to access outside the ACOs to verify that savings are not achieved at the cost of improved care. For cancer care, in particular, CMS also should monitor the timeliness of ACOs' adoption of the most current compendia guidance on use of drugs and biologicals. The statutory provisions on coverage of off-label uses of drugs in anti-cancer chemotherapeutic drug regimens¹⁷ are critical to ensure that Medicare beneficiaries have access to the most appropriate cancer care. If CMS finds that beneficiaries in an ACO have less access to the current standard of care than patients outside the ACO, the agency should take corrective action against the ACO.

VIII. CMS should develop a system to better account for beneficiaries that do not receive all of their care from one ACO.

The Proposed Rule does not address the issue of Medicare beneficiaries that receive their care in more than one location. Many Medicare beneficiaries receive care in two or more geographic locations in a year, such as rural New York State and Miami, Florida. Although such beneficiaries may be assigned to an ACO based on the location in which they receive the plurality of primary care services, it would in fact be difficult for the ACO to effectively manage the beneficiary's care when he or she spends a significant amount of time in a different location. The ACO also would be accountable for the expenditures and quality of care provided to the beneficiary in the alternate location that may have different standards of practice. ACCC believes it is important for CMS to create a system to track these types of patients and take steps to ensure that it is appropriate to hold the ACO to which the patient is assigned accountable for all of the patient's care.

¹⁶ Id. at 19604-05.

¹⁷ Social Security Act § 1861(t)(2).

IX. CMS should work with entities already engaged in cost-saving activities to ensure that they can participate in the MSSP or similar programs.

There are many prospective ACOs that already are engaged in quality improvement and cost reduction activities that also may have a difficult time applying to participate in the MSSP. In addition to completing the long and in-depth application process to apply to be an ACO, entities that already have begun to function like an ACO may have trouble showing that they will achieve further savings because they already are operating very efficiently. ACCC urges CMS to work with these entities to help them participate in the MSSP or similar programs under the CMMI. CMS could accomplish this by streamlining the application process under the MSSP or working with these entities to develop alternative demonstration programs in which they can participate.

X. CMS should not withhold shared savings in order to ensure that funds will be available for risk-sharing.

CMS is proposing to withhold 25 percent of annual earned performance payments from ACOs.¹⁸ CMS believes that such withholding is necessary to ensure repayment to CMS for potential future losses and also to provide an incentive for ACOs to participate for the full three years of an agreement. ACCC believes that withholding any portion of the shared savings from an ACO will further discourage participation in the program. As already mentioned, the high start-up costs, along with risk-sharing, are major considerations for providers in making a cost-benefit analysis of joining an ACO. By withholding potential payments, money that could be used right away to further improve quality in the hospital or practice, CMS is discouraging participation even further.

ACCC understands CMS's justification for the proposal, but believes that other CMS proposals not only are sufficient to achieve this goal, but also will not discourage participation. First, an ACO that achieves shared savings in one year already has a strong incentive to continue to participate in the program to achieve additional savings in subsequent years. Also, requiring ACOs to establish a self-executing method for repaying losses to the Medicare program, as CMS proposes, will provide sufficient assurances that the program will be repaid. These mechanisms protect the integrity of the MSSP while allowing ACOs to use the shared savings to which they are entitled.

¹⁸ 76 Fed. Reg. at 19615.

Donald M. Berwick, MD

June 2, 2011

Page 10 of 10

XI. Conclusion

ACCC appreciates the opportunity to submit these comments. We look forward to participation from community oncology providers, and we would like to serve as a resource for CMS as you develop the final rule for ACOs. Please contact Sydney Abbott, at sabbott@acc-cancer.org with any comments or questions. Thank you again for your consideration of these very important issues.

Respectfully,

A handwritten signature in black ink, reading "Thomas L. Whittaker". The signature is written in a cursive style with a long, sweeping underline.

Thomas L. Whittaker, MD, FACP

President

Association of Community Cancer Centers