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February 6, 2015

Administrator Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

BY ELECTRONIC DELIVERY

**RE: Medicare Program; Medicare Shared Savings Program: Accountable
Care Organizations (CMS-1461-P)**

Dear Administrator Tavenner:

On behalf of the Association of Community Cancer Centers (ACCC), we appreciate this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule regarding the Medicare Shared Savings Program (MSSP) and Accountable Care Organizations (ACOs).¹

ACCC represents more than 20,000 cancer care professionals from approximately 1,100 hospitals and more than 1,000 private practices nationwide. These include Cancer Program Members, Individual Members, and members from 32 state oncology societies. It is estimated that 60 percent of cancer patients nationwide are treated by a member of ACCC. Similar to the Centers for Medicare & Medicaid Services (CMS), ACCC is committed to improving health outcomes for Medicare beneficiaries.

ACCC applauds CMS's ongoing efforts to refine the MSSP to ensure that the program achieves its goals related to improving accountability for a patient population, coordination of items and services under Medicare Parts A and B, and

¹ 79 Fed. Reg. 72,759 (December 8, 2014).

the quality and efficiency of health care service delivery by encouraging investment in infrastructure and redesigned care processes. Community cancer centers play an important role in the health care system, and we know that they can be critical to helping ACOs achieve these goals. To that end, we offer the following recommendations for CMS's consideration as the agency continues to improve the ACO program:

- I. CMS should adopt its proposal to take into account primary care services provided by nurse practitioners, physician assistants, and clinical nurse specialists for purposes of assigning beneficiaries to an ACO in Step 1.
- II. CMS should use regional fee-for-service expenditures instead of national fee-for-service expenditures in establishing and updating the benchmark for ACOs.
- III. CMS should adopt its proposal to allow ACOs to continue participating under a one-sided participation agreement after their first 3-year agreement but should not decrease the financial attractiveness of this model.
- IV. CMS should adopt its proposal to reduce the level of risk for which ACOs could be responsible under the two sided Track 2 model.
- V. CMS should adopt its proposal to offer a new two-sided ACO model (Track 3) in which beneficiaries are assigned to an ACO prospectively, but should consider more carefully how to handle beneficiaries assigned to the ACO prospectively but who ultimately obtain most of their care outside the ACO.
- VI. CMS should adopt its proposal to waive certain payment and program requirements related to the use of telehealth technologies to increase access to care and better care coordination but should also ensure appropriate patient safeguards.
- VII. CMS should require ACOs to publicly report additional information as proposed by CMS, and make available online ACO-specific information.
- VIII. CMS should consider the creation of oncology-centered ACOs under the Center for Medicare and Medicaid Innovation (CMMI) and move forward with medical oncology and radiation oncology demonstrations.
- IX. CMS should encourage ACOs to participate in clinical trials.
- X. CMS should encourage future development of life-saving cancer treatments by excluding the costs of innovative technologies from the assessment of an ACO's savings and by monitoring access to these technologies.
- XI. CMS should use quality measures on treatment of cancer that ensure beneficiaries receive appropriate cancer care.
- XII. CMS should develop a system to better account for beneficiaries that do not receive all of their care from one ACO.
- XIII. CMS should institute protections to ensure that ACOs do not game the system and that beneficiaries have access to appropriate cancer therapies.

Please see our comments below for additional information regarding each of these recommendations.

I. CMS should adopt its proposal to take into account primary care services provided by nurse practitioners, physician assistants, and clinical nurse specialists for purposes of assigning beneficiaries to an ACO in Step 1.

Under the current MSSP beneficiary assignment methodology, care received from nurse practitioners, physician assistants, or clinical nurse specialists is considered during Step 2 of the assignment process, which only applies to Medicare beneficiaries who have not received any primary care services from a primary care physician. In the Proposed Rule, CMS proposes to revise its beneficiary assignment methodology to take into account primary care services furnished by nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs) in Step 1 of the assignment process. This change would mean that services furnished by NPs, PAs, and CNSs would be taken into account for every Medicare beneficiary eligible for assignment to an ACO in order to determine the ACO from which the beneficiary receives a plurality of primary care services.²

ACCC supports this proposed change. Non-physician practitioners often play an especially important role in the management of patients with complex conditions, such as cancer. Oncologists often work closely with NPs, PAs, and CNSs in providing primary care services to cancer patients and thus these non-physician practitioners help to expand the cancer careforce. As such, we believe that this proposed change would more accurately reflect how these beneficiaries receive their primary care. Non-physician practitioners also play a vital role in ensuring access to primary care services for many Medicare beneficiaries in areas where there is a shortage of primary care physicians and in rural areas. For these reasons, as well as the fact that this change would better align MSSP's beneficiary assignment methodology and the Patient Protection and Affordable Care Act's emphasis on primary care, we urge CMS to adopt this proposal.

II. CMS should use regional fee-for-service expenditures instead of national fee-for-service expenditures in establishing and updating the benchmark for ACOs.

Under the current MSSP regulations, CMS uses national expenditure data in establishing the benchmark for ACOs. As CMS notes, some stakeholders, including ACCC, have expressed concern that the current benchmarking methodology doesn't sufficiently account for the effect of regional or local cost trends on the ACO's performance. CMS is now considering using regional, rather than national, fee for service expenditures in establishing benchmarks, similar to the approach used in the Physician Group Practice (PGP) demonstration.

ACCC supports the use of regional, rather than national, factors in establishing and updating ACO benchmarks. Consistent with the comments we made on the proposed ACO rule in 2011,

² *Id.* at 72, 795-98.

we believe using regional expenditures and growth rates would more appropriately reflect the experiences of ACOs in different geographic areas, and would help address concerns that using national figures might create financial incentives to develop ACOs in some parts of the country and discourage them in others, based on the costs in those areas relative to the national average.

III. CMS should adopt its proposal to allow ACOs to continue participating under a one-sided participation agreement after their first 3-year agreement but should not decrease the financial attractiveness of this model.

The current regulations allow ACOs to participate under the one sided shared savings model (Track 1) only for their initial 3 year agreement period, after which they're be required to transition to the two-sided model (Track 2) in which they would also share risk. CMS now proposes to allow ACOs that meet certain performance criteria to continue participating in Track 1 for a second agreement period. However, in order to encourage ACOs to transition to a model in which they bear a certain amount of financial risk, which CMS believes will encourage more meaningful systemic changes, CMS proposes to reduce the potential for shared savings by 10 percent during a second agreement period in Track 1.

ACCC appreciates and supports CMS's proposal to allow ACOs to continue operating under the Track 1 model for a second agreement period. Developing and learning to operate an accountable care organization is an enormous transition for the health care industry. The learning curve is more of a challenge for some organizations, and some face more stumbling blocks than others. We urge CMS to be patient as health care providers and administrators learn the ropes of this new way of delivering and coordinating health care services. We also would discourage CMS from reducing the potential shared savings during a second agreement period in Track 1. Assuming that ACOs are meeting the criteria for participation in a second agreement period, and have signaled their desire to continue participating in the MSSP, they should be encouraged to continue working towards a time when they are willing and able to assume shared risk, and should not be punished for needing a longer on-ramp.

IV. CMS should adopt its proposal to reduce the level of risk for which ACOs could be responsible under Track 2.

As part of the effort to encourage ACOs to accept increased performance-based risk, CMS also is proposing to modify the threshold that Track 2 ACOs have to meet or exceed in order to share in savings or losses. CMS believes that by building in more protection, more ACOs may be willing to transition to a model in which they assume performance based risk.

ACCC supports this proposal and agrees that a model that is more protective may attract more participation by ACOs. As noted above, the move to serving beneficiaries through an

accountable care organization is a significant transition and it involves coordinating many facets of a complex care delivery system and learning to manage populations, which is new to most organizations. We believe that providing more of a safety net will encourage participation by additional ACOs that want to transition to a performance based risk model but are anxious about doing so.

CMS also seeks comment on whether the prospective assignment approach proposed in the new Track 3 model also should be implemented in Track 2. Based on the concerns expressed below in our comments regarding the Track 3 model, we would encourage CMS not to use prospective assignment of beneficiaries in Track 2 at this time. While we are supportive of CMS's development of the Track 3 option, and look forward to seeing how it works, we believe ACOs that are willing to assume performance based risk should have the option of participating in the current Track 2 model with retrospective reconciliation to add or remove beneficiaries assigned to the ACO, or in the new model in which beneficiaries are prospectively assigned with virtually no reconciliation at the end of the year.

V. CMS should adopt its proposal to offer a new two-sided ACO model (Track 3) in which beneficiaries are assigned to an ACO prospectively but should consider more carefully how to handle beneficiaries assigned to the ACO prospectively who ultimately obtain most of their care outside the ACO, including those diagnosed with cancer during the performance period.

Under the current assignment methodology for the Track 1 and Track 2 models, beneficiaries are preliminarily assigned to an ACO on a prospective basis and then a retrospective reconciliation is performed before a final assigned beneficiary list is generated. CMS now proposes to create a new Track 3 model in which beneficiaries would be prospectively assigned to an ACO at the start of a performance year, and only a very limited reconciliation would be performed to remove, but not add, only those beneficiaries that no longer meet eligibility criteria. CMS believes this would give ACOs more certainty about the population for which they'll be responsible, and on whom to focus their care redesign efforts.

ACCC is supportive of CMS's proposal to add a new Track 3 model as an option for ACOs, but we do have concerns about the effect that prospective assignment may have on ACOs that are held accountable for beneficiaries with whom the ACO may ultimately have had little contact during the year. For example, a beneficiary may be prospectively assigned to an ACO and then early in the performance year may be diagnosed with cancer. The beneficiary may obtain most of their care during the year from providers not participating in the ACO, and the ACO therefore may have little or no ability to coordinate or affect the services they receive, yet the ACO would still be accountable for that beneficiary under the proposed Track 3 model. While we certainly hope that ACOs would develop systems to provide comprehensive care to beneficiaries assigned to the ACO who are diagnosed with cancer, and that those beneficiaries

would be able to obtain all necessary care within the ACO, that will not always be possible. While we understand that ACOs would have the option of deciding whether they wished to participate in the Track 3 model, and assume the risks of prospective assignment, we encourage CMS to consider the consequences of holding ACO's responsible for beneficiaries who, for legitimate reasons, may end up obtaining most of their care outside the ACO.

VI. CMS should adopt its proposal to waive certain payment and program requirements related to the use of telehealth technologies but should also ensure appropriate patient safeguards.

In order to encourage more ACOs to participate in two sided performance-based risk models, CMS seeks comment on whether it may be necessary and appropriate to provide additional flexibility regarding certain program requirements, including potentially waiving certain program rules, such as those related to the provision and payment for telehealth services. Currently, coverage of telehealth services requires that it be provided via an interactive telecommunications system, to an "eligible telehealth individual," and they must be in an "eligible originating site."

We support CMS's proposal to allow the waiver of certain program requirements to permit ACOs to use telehealth services more extensively and more creatively to increase beneficiary access to care and to better coordinate care. We believe telehealth has tremendous potential to expand access to services that may not otherwise be available to certain beneficiaries, particularly those in rural areas or who have difficulty travelling to health care facilities, and to allow patients to access services where, when and how they're most beneficial. However, we share CMS's concern that ACOs be monitored to ensure that telehealth services are not used as a substitute for necessary in-person services, and we also support CMS's plan to impose certain safeguards, such as requiring ACOs to submit a plan describing how it would use the waiver to meet the clinical needs and enhance the care provided to its assigned beneficiaries, and we encourage CMS to monitor the quality of care provided to beneficiaries who receive telehealth services under such a waiver. We also encourage CMS not to limit the availability of these waivers only to ACOs participating in the Track 3 model.

VII. CMS should require ACOs to publicly report additional information as proposed by CMS and make available online ACO-specific information.

In the Proposed Rule, CMS proposes to broaden ACO reporting requirements as well as ACO-specific information that is posted online. In addition to existing reporting requirements, CMS proposes to require that ACOs also publicly report information on (1) key clinical and administrative leadership within the ACO; (2) the types of ACO participants or combinations of ACO participants that form the ACO; and (3) ACO performance on all quality measures

used to assess the quality of care furnished by the ACO. CMS proposes to post online ACO-specific information that the ACO is required to report publicly.

ACCC fully supports both transparency in healthcare as well as patient-centeredness and thus supports these proposed requirements. Transparency fosters patient-centeredness by giving patients the tools they need to make informed decisions about where to seek care. In addition, transparency holds ACOs accountable by facilitating oversight and can also drive improvements in care and innovation. Transparency also can help to reduce fraud and abuse in the health care system. For all of these reasons, we encourage CMS to move forward with implementing these proposed requirements to enhance the transparency of the MSSP.³

VIII. CMS should consider the creation of oncology-centered ACOs under the CMMI and move forward with medical oncology and radiation oncology demonstrations.

CMS uses the provision of primary care to assign beneficiaries to ACOs, and many of the quality measures used to evaluate ACOs assess their performance on the provision of primary care services. Aspects of the MSSP such as these underscore the program's emphasis on primary care.

The circumstances surrounding the care of a cancer patient, however, are more complex. Once a patient is diagnosed with cancer, the patient's care is primarily in the hands of oncologists and other specialists. Now that CMS has had some time to refine a primary care-centric ACO model, an appropriate next step would be for CMS to enhance the program by seeking to improve care coordination for those with more complex conditions such as cancer.

To this end, we urge CMS to consider the creation of oncology-centered ACOs under the authority of the CMMI, to better assess the ability of ACOs to provide high quality, well-coordinated cancer care. Patients would be assigned to these ACOs based on the care they receive from those specialists most commonly involved in the treatment of 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 know that private payers and providers have been involved with oncology-centric ACOs since the launch of Medicare's ACO program. For instance, First Coast in Florida has created oncology ACOs with two hospitals: Moffitt Cancer Center in Tampa and Baptist Hospital in Miami. Programs such as these can serve as models as CMS develops a larger oncology-centric ACO model. Patients with conditions such as cancer have complex needs. We anticipate that patient outcomes would be better and the costs of care would be lower when

³ *Id.* at 72,846-47.

care for such patients is well-coordinated. ACCC would be happy to meet with CMS to discuss this idea further.

We recognize that CMS seeks to shift its programs toward value-based delivery models. We believe that implementation of a medical oncology demonstration as well as a radiation oncology demonstration would align well with CMS's value-based purchasing efforts and simultaneously help to advance CMS's care coordination agenda. We appreciate CMMI's work on the Oncology Care Model and its willingness to meet with us to discuss the potential demonstration. We look forward to the release of an updated draft this spring that reflects stakeholder input to date and allows for additional public comment. We understand that CMS is also contemplating a radiation oncology demonstration. We strongly support both of these demonstration efforts and would be happy to serve as a resource as CMS works to finalize implementation details.

IX. CMS should encourage ACOs to participate in clinical trials.

In the field of oncology, many advances in care involve the development of new therapies as well as the discovery of new uses for existing therapies. Clinical trials evaluating such therapies are critical to helping beneficiaries obtain access to innovative care and also help to improve the standard of care for all patients. In fact, for Medicare beneficiaries battling cancer, the most appropriate care may be available only in a clinical trial setting. Thus, particularly as CMS shifts more toward value-based delivery models, ACOs should be encouraged to protect access to specialty care available in the research setting. We suggest that CMS accomplish this goal by requiring ACOs to participate in clinical trials, awarding "bonus points" to ACOs that participate in clinical trials to increase their shared savings rate, or incorporating quality measures into the ACO program that encourage clinical trial participation.

X. CMS should encourage future development of life-saving cancer treatments by excluding the costs of innovative technologies from the assessment of an ACO's savings and by monitoring access to these technologies.

ACCC recognizes that risk-bearing arrangements such as the MSSP create incentives for providers to minimize costs. Such incentives may discourage providers from using potentially high-cost, innovative treatments that may not yield savings within the relevant time period for measuring the ACOs' performance, and yet could produce better outcomes for the patient and savings for the Medicare program over the long-term. ACCC is particularly concerned about the effects that such incentives have on the development of innovative cancer treatments. CMS should implement mechanisms to counteract such incentives and thereby ensure that patients have access to state-of-the-art care and continued innovation.

To protect access to innovative care and align Medicare incentives for appropriate use of new technologies under the fee-for-service and ACO payment methodologies, we recommend that CMS carve-out from the benchmark and performance year expenditures those new technologies that are already subject to special payment provisions under other Medicare payment systems. Under this proposal, 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. More specifically, we believe that drugs, biologicals, and devices that are granted transitional pass-through payment status under the outpatient PPS or technologies that receive new technology add-on payment under the inpatient PPS should be excluded from the shared savings calculations and from any capitated payment rates for ACOs. Although these existing protections do not extend to the physician office settings, we believe that this new technology exclusion should apply to these same products used in physician offices. Implementing these carve-outs will help to ensure that an ACO's decision to use a new treatment will not affect the calculation of the ACO's expenditures for purposes of determining whether shared savings were generated, and the ACO therefore will not have an incentive to lower costs by denying patient access to the therapy.

Finally, we urge CMS to monitor ACOs for changes in beneficiary access to new technologies. To ensure that ACO savings are not achieved at the cost of improved care, CMS should compare access to new technologies for beneficiaries within ACOs to access outside the ACOs. In addition, to provide safeguards for Medicare beneficiaries with cancer, we urge CMS to monitor the timeliness of ACOs' adoption of the most current compendia guidance on use of drugs and biologicals. The statutory provisions allowing for coverage of off-label uses of drugs in anti-cancer chemotherapeutic drug regimens⁴ are essential to ensuring that Medicare beneficiaries have access to the most appropriate cancer care. If CMS finds that beneficiaries in an ACO have more restricted access to the current standard of care than patients outside the ACO, the agency should take corrective action against the ACO.

XI. CMS should use quality measures on treatment of cancer that ensure beneficiaries receive appropriate cancer care.

CMS should incorporate into the MSSP quality measures that encourage ACOs to ensure that beneficiaries receive appropriate cancer care. At this time, the MSSP includes a breast cancer screening measure and a colorectal cancer screening measure, but no measures regarding treatment of cancer. ACCC supports inclusion of these screening measures, as they help to promote appropriate detection of certain cancers. However, on their own, they are not sufficient to protect and promote quality cancer care by ACOs. We urge CMS to incorporate into the ACO program quality measures that have been endorsed by a national, consensus-

⁴ Social Security Act § 1861(t)(2).

based organization such as National Quality Forum or Joint Commission. Further, CMS should seek to incorporate into the MSSP consensus-based, endorsed quality measures on cancer care that are used in Medicare's other quality programs to align quality measurement across programs.

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

Many Medicare beneficiaries receive care in two or more geographic locations in a year, such as rural New York state and Miami, Florida. However, under the MSSP, such beneficiaries are assigned to only one ACO based on certain factors, including the location in which the beneficiary received the plurality of his or her primary care services. This methodology may have a negative impact on the ACO to which the beneficiary is assigned. In such cases, it may be difficult for the ACO to which the patient is assigned to manage effectively the beneficiary's care throughout the year. In addition, the ACO to which the patient is assigned will be held accountable for expenditures and quality of care provided to the beneficiary in the alternate location, which may have different standards of practice. We believe that CMS should strive to create a system that tracks these types of patients and take steps to verify the appropriateness of holding the ACO to which the patient is assigned accountable for all of the patient's care. CMS may also wish to consider a mechanism to limit an ACO's shared losses (or shared gains) in such circumstances.

XIII. CMS should institute protections to ensure that ACOs do not game the system and that beneficiaries have access to appropriate cancer therapies.

ACCC encourages CMS to implement additional protections to prevent ACOs from engaging in cost shifting and taking other steps to game the system. Currently, ACOs are not responsible for the expenses of Part D drugs. ACCC remains concerned that this structure may create incentives for ACOs to make decisions about cancer patients' treatment based on the effects on the ACO's total costs, rather than clinical evidence, as ACOs may shift patients to Part D therapies even if those therapies are not the most optimal clinical choice for the Medicare beneficiary. In addition, increased cost-sharing under Part D, as compared to Part B, may negatively affect beneficiaries' adherence to the prescribed regimen and, in turn, lead to poor outcomes. ACOs should not be rewarded when they achieve savings by shifting costs in this manner.

We strongly believe that cancer patients should have access to the most appropriate therapies for their particular type and form of cancer, and we have become increasingly concerned about the misaligned incentives discussed above as more oral oncolytics come to market. To help address these concerns, we believe that CMS should hold ACOs accountable for Part D expenses while also implementing beneficiary protections. At minimum, we believe that CMS

should require ACOs to (1) comply with the minimum formulary review and transparency requirements applicable to Part D plans; (2) comply with the current out-of-pocket cost limits under Part D; (3) provide convenient access to drugs by complying with the requirements applicable to Part D sponsors to secure broad participation in pharmacy networks; and (4) protect beneficiaries' choice of providers by allowing out-of-network access to drugs if they choose to receive their prescriptions from pharmacies outside the ACOs. In addition, we urge CMS to monitor ACOs to ensure that they do not employ unduly restrictive utilization management techniques that deny or delay access to the most appropriate therapies. We believe that these measures will ensure that ACO efforts to control costs do not interfere with patients' access to necessary therapies.

XIV. Conclusion

ACCC appreciates the opportunity to submit these comments and CMS's ongoing efforts to continue to refine the ACO program. If you have any questions about our comments or if ACCC can be of further assistance, please contact Leah Ralph, Manager of Provider Economics and Public Policy, at 301-984-5071. Thank you again for your consideration of these very important issues.

Sincerely,

A handwritten signature in black ink that reads "Rebecca L. DeKay". The signature is written in a cursive, flowing style.

Becky L. DeKay
President
Association of Community Cancer Centers