

701 Pennsylvania Ave., NW, Suite 800
Washington, DC 20004-2654
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org



March 28, 2016

Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-1644-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations—Revised Benchmark Rebasing Methodology Proposed Rule

Dear Acting Administrator Slavitt:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am pleased to offer comments on the proposed rule published in the *Federal Register* February 3, 2016. AdvaMed has been a strong supporter of accountable care organizations (ACOs) since their inclusion in the Affordable Care Act. We recognize the importance of the goals of ACO initiatives as they seek to improve both the efficiency and quality of health care in this country, and our members' technologies can play a critical role in assisting providers to achieve these goals. Our member companies do so through advances in medical devices, diagnostics, and other advanced medical technologies. These products and services improve patient care quality and many improve efficiency by reducing the lengths of stay of patients in health care facilities, allowing procedures to be performed in less intensive and less costly settings, providing early detection of disease and infections, and improving the ability of providers to monitor care, among other benefits.

In this letter, we offer comments on the need for adjustments to benchmark and total expenditures calculations in order to ensure Medicare beneficiary access to all appropriate treatment options, including innovative medical technologies

Ensuring Patient Access to Appropriate Care

AdvaMed supports delivery reform models, including ACOs, and their goals to achieve lower cost and higher quality health care. At the same time, we are concerned that the financial incentives in these and other delivery reform models can have the inadvertent effect of discouraging providers from (1) considering the full array of treatment options, especially if they may increase costs above "benchmark" thresholds—we refer to this as stinting, or (2) using innovative treatments, technologies, and diagnostics

that may bring value to the health care system over the longer term, but are more costly in the short run. The potential negative impact of the financial incentives of these models is magnified by the short payment windows used in the programs to compare actual spending against benchmarks in order to determine the level of savings that may be shared among providers. Many medical devices and technologies provide benefits over a long period of time spanning multiple years.

CMS stated in the final rule for the MSSP program published in the Federal Register June 9, 2015 that the agency does not believe that adjustments beyond the IME and DSH adjustments currently allowed in the program are necessary at the present time. We nevertheless continue to argue that adjustments for certain new technologies are necessary to ensure Medicare beneficiaries access to the full range of treatment options and new technologies considered by their providers as appropriate for their medical conditions—to the extent these are more expensive than a current standard of care. We offer examples below as to why we think such adjustments are necessary. In addition, we point out that we do not expect that many new treatments and technologies will require such technologies.

Data analysis by one of our member companies points to the potential impact the financial incentives in the ACO model and the relatively short timeframes for measuring savings can have on care received by Medicare beneficiaries in these models. The specific data analysis done by our member company focused on utilization rates for several interventional treatment options for arterial procedures and utilization rates of these options for Medicare beneficiaries served by ACOs. The analysis showed an increase in utilization of a lower cost procedure option and a decrease in utilization of a higher cost alternative procedure for patients served by ACOs. The increase in utilization of the lower cost option could mean more frequent re-interventions for patients in the future, with the result that higher savings for ACOs in the short-term could also mean higher long-term spending for the Medicare program in the subsequent years.

Additionally during the past year, some of our orthopedic company members have learned that certain providers participating in the Innovation Center's Bundled Payments for Care Improvement (BPCI) initiative have radically changed the type of hip and knee implants that they buy and use in patients. While this change is related to the highly targeted incentives in BPCI, the same incentives exist for an ACO and this activity should be considered under the MSSP and Innovation Center ACOs.

In the past, these hospitals had purchased a range of device implants—including some implants that are more basic, without newer features and with varying levels of performance characteristics that improve range of motion or impact durability (e.g., lower utility implants). Providers made implant selection decisions that corresponded to the particular lifestyle needs of patients, including life expectancy, level of activity, and medical conditions. This process is called demand matching and is an effective method in managing utilization without limiting access to technologies that best meet individual patient needs. With participation in BPCI, these providers now purchase almost exclusively lower utility implants without respect to patient needs. Matching the utility of a device to a particular patient's need is critical to ensuring a positive outcome for the patient and long-term effectiveness of the procedure. For example, an active, tennis-playing 65-year old requires a hip or knee of higher utility and performance characteristics than one that is appropriate for a sedentary 85-year old.

While it is possible that the patient mix of Medicare beneficiaries treated by the providers has changed since participation in BPCI began, it should be pointed out that lower utility devices are also initially less expensive than the higher utility devices, leading to potentially higher internal savings that can be shared in the short term. The longer term impact of using almost exclusively lower utility devices, when they may not be appropriate for the lifestyle and medical needs of individual patients, may not be known for several years, when active beneficiaries may require earlier than expected revision procedures or experience other negative outcomes. If the choice of a hip or knee device were made solely on the basis of patients' relative health, lifestyle and life expectancy, patients would be provided a device that appropriately demand matched to their unique needs with cost not being a leading driver of this decision so as to ensure the best possible outcomes and longevity.

In addition, quality standards used for ACOs could discourage early adoption of new and better alternative treatments simply because the quality measures do not reflect breakthrough and innovative treatments. If a new approach to care is developed that may be superior to standard practice, and no special exception is provided for the new alternative treatment, physicians or hospitals may avoid adopting it because it will lower the ACO's quality score and, in turn, reduce shared savings. We have learned from the Innovation Center that physicians in Pioneer ACOs have asked to be able to use a new and more effective pneumococcal pneumonia vaccine instead of an older vaccine that is specified in a process quality measure used for both the MSSP and Pioneer programs. The problem that physicians in these ACOs face is a reduction in their quality scores if they do choose to use the new vaccine, simply because this particular measure does not yet reflect a new standard of care and because no special exception is allowed for physicians to use the innovation. Patients may not be harmed by the old vaccine but they are not, at the same time, provided the benefits of the new product. This is another good example of how a technical adjustment in ACO programs can provide Medicare beneficiaries the benefits of innovations in health care without undermining the overarching goals of the program.

Another instance of existing quality measures used in ACO programs impeding beneficiary access to innovative technologies involves two new and less invasive screening options for colorectal cancer. These new technologies include a new imaging screening tool, and Cologuard, an at-home non-invasive colon cancer screening test for evaluating DNA mutations and blood in the stool. This latter screening tool was simultaneously approved by FDA and covered by CMS through parallel review in August 2014. The existing ACO quality measure for colorectal screening, however, recognizes only a fecal occult blood test, flexible sigmoidoscopy, and colonoscopy (the latter two according to a specified periodicity schedule). These screening methods have patient compliance issues that lower screening rates. A provider wishing to use the innovative technologies would be penalized, as described in the previous example, for using the new screening tools instead of one of the three previously named tools specified in the quality measure. Once again, a technical adjustment would provide Medicare beneficiaries the benefits of innovations in health care while enhancing quality of care available to patients.

These negative impacts can be avoided without undercutting the goals of the new payment and delivery systems by incorporating certain technical adjustments in the programs and by adopting other patient protection measures. We believe that these technical adjustments and patient protections become even more important for beneficiaries if CMS and CMMI allow ACOs and other delivery reform models to assume more risk for the cost of care.

AdvaMed notes that CMS has acknowledged the impact a higher cost innovative technology can have on providers' ability or interest in using that technology in patient care when they participate in delivery reform models, specifically BPCI and the Comprehensive Care for Joint Replacement (CJR) bundled payment model. The Innovation Center has approved carve outs of IPPS new technology add-on payments (NTAPs) from both the actual historical episode expenditure data used to set target prices and from the hospital's actual episode spending that is reconciled to the target price for providers participating in these programs. In proposing the carve out of NTAP amounts for the CJR model, CMS noted that it would not be appropriate for the model to potentially hamper beneficiaries' access to new technologies that receive NTAPs or to burden hospitals who choose to use these new technologies with concern about these payments counting toward actual expenditures. AdvaMed recommends that this policy be extended to ACOs, both the MSSP program and Innovation Center ACOs.

Furthermore, AdvaMed believes that additional innovative technologies, beyond NTAPs, should qualify for similar adjustments to calculation of benchmark and actual expenditure totals. In brief, our recommendation would provide adjustments for a limited number of innovative treatments or diagnostics that are first reviewed and approved by CMS after meeting certain criteria. These adjustments would be used for a limited period of time to allow time for these treatments and diagnostics to be reflected in new benchmarks or incorporated in quality measurement to the extent they become the standard of care. For purposes of payment for innovative treatments, the cost of approved innovative treatments would be removed from the calculation of benchmarks and Medicare expenditures when calculating savings or losses. Where the barrier to adoption is a quality standard, quality measurement would exclude the case with the new treatment from the provider or physician quality score. With these adjustments, the disincentives to use an innovative treatment or diagnostic would be neutralized and ACO providers would make decisions purely on medical grounds.

Finally with regard to the proposed rule's consideration of methodologies for ACO second and subsequent participation agreement periods, our concern is with any methodology that results in ever greater pressure on efficient providers to continue to achieve savings that would pose ever greater risk for patients in the form of stinting on care and compromised patient access to appropriate treatment options and innovative technologies—risks that are already inherent to shared savings models. AdvaMed supports options that do not penalize ACOs for savings achieved in prior years in calculating benchmarks and that would protect patient access to all appropriate care options.

We appreciate the opportunity to offer these comments. If you have any question, please contact me or Richard Price at rprice@advamed.org or 202-434-7227.

Sincerely,

/s/

Don May
Executive Vice President,
Payment and Health Care Delivery