MDMA
MEDICAL DEVICE MANUFACTURERS ASSOCIATION

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June 6, 2011

Donald M. Berwick
Administrator
Centers for Medicare and Medicaid 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 Proposed Rule (CMS-1345-P)

Dear Dr. Berwick:

The Medical Device Manufacturers Association (MDMA) appreciates the opportunity to provide comments on the Medicare Shared Savings Program (MSSP): Accountable Care Organizations (ACOs) proposed rule (the "Proposed Rule").[1] MDMA represents hundreds of innovative medical technology companies, and our goal is to ensure that patients have timely access to safe and effective medical treatments, including the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

MDMA supports the three general goals of the MSSP: "better health care for individuals," "better health for populations," and "lower growth in expenditures by eliminating waste and inefficiencies while not withholding any needed care that helps beneficiaries."[2] Our members are dedicated to developing medical devices that can help achieve these goals, but their investments will succeed only if Medicare and other payers provide appropriate incentives for physicians and providers to use these innovative products. In the Proposed Rule, CMS recognizes that risk-based payment arrangements could lead to increased "negative incentives such as incentives to stint on care or undersupply services, [and] shift costs (for instance through changes in referral patterns)."[3] CMS seeks to protect against these incentives by incorporating quality measures into the assessment of each ACO's performance and by requiring ACOs to implement "evidence-based medical practice or clinical guidelines"[4] consistent with the three goals for the MSSP. MDMA agrees with the intent of these measures, but they need to be strengthened if they are to be effective at protecting quality care and encouraging continued innovation. In particular, we recommend that CMS:

1. Carve out new technologies from the expenditures used to evaluate an ACO's performance;

[1] 76 Fed. Reg. 19538 (April 7, 2011).
[2] Id. at 19533.
[3] Id. at 19617.
[4] Id. at 19644.

2. Encourage appropriate use of innovative technologies through consensus-based quality measures that promote timely referrals to specialists and are updated frequently to reflect improvements in treatment options; and

3. Require ACOs to include specialists in the groups that are responsible for selecting medical practice guidelines.

We discuss these proposals in detail below.

I. CMS should carve out new technologies from the expenditures used to evaluate an ACO's performance.

CMS proposes to assess each ACO's performance by comparing its expenditures to a benchmark based on expenditures for beneficiaries who would have been assigned to the ACO in the three years prior to the agreement period.[5] The benchmark expenditure data will be adjusted by a growth health status indices,[6] but these adjustments would not account for the costs of new technologies that become available during the agreement period. MDMA is concerned that ACOs might be reluctant to use new technologies, even if they help reduce the costs of care over the long term, if the costs of using those technologies during the agreement period appear high compared to the benchmark expenditures. As CMS correctly observes, ACOs should be encouraged to "invest to improve quality and efficiency of care" and not to "generate savings resulting from inappropriate limitations on necessary care."[7] CMS can encourage ACOs to make these investments and protect access to necessary care by ensuring that ACOs are not penalized for using innovative technologies that improve the quality of care.

We urge CMS to consider the options available for carving these expenses out of the data used to measure an ACO's performance. Under one possible approach, CMS could exclude the costs of any technology that is granted a new technology add-on payment under the hospital inpatient prospective payment system (PPS) or pass-through status under the hospital OPPS from the benchmark and the ACO's expenditures. These mechanisms are intended to provide adequate payment for technologies that would not be reimbursed appropriately under the standard Medicare payment methodologies. Consistent with the efforts to protect access to these technologies under the IPPS and OPPS, CMS should ensure that ACOs are not penalized for using these technologies under the MSSP by excluding their costs from the benchmark and the ACO's expenditures used to calculate shared savings.

II. CMS should encourage appropriate use of innovative technologies through consensus-based quality measures that are updated frequently to reflect improvements in treatment options and promote timely referrals to specialists.

CMS proposes to use a set of 65 quality measures to determine if an ACOs is eligible to receive shared savings.[8] We support the goal of promoting quality along with efficiency, and we are pleased that CMS plans to align the measures used for the MSSP with Medicare's other quality

[5] Id. at 19604.
[6] Id. at 19605.
[7] Id. at 19615.
[8] Id. at 19570.

programs.[9] We also support CMS's plan to refine and expand the measures in future rulemakings.[10] As innovative devices and other technologies contribute to the evolution of the standard of care for many conditions, Medicare's quality measures also must evolve to promote the best quality care for beneficiaries. Indeed, failure to revise existing quality measures or to establish new measures for changes in treatment options would provide a perverse incentive to ACOs, potentially rewarding them for providing sub-standard care. CMS should work with stakeholders and consensus-based organizations to identify outdated measures, revise existing measures to reflect changes in treatment options, and to develop measures for appropriate use of new technologies for which no measures currently exist. The consensus-based organizations are best equipped to consider the relevant literature and expert opinion and develop meaningful measures that effectively promote high-quality care.

In addition to reflecting appropriate use of innovative technologies, the quality measures used in the MSSP also should promote timely referrals to specialists. CMS intends for primary care physicians to improve the quality and efficiency of care by coordinating with the specialists who treat their patients.[11] This coordination role must include new referrals to specialists, as well as working with the specialists already treating each beneficiary, but the Proposed Rule does not address protections to ensure that beneficiaries are referred to specialists in a timely manner. Although CMS reiterates throughout the Proposed Rule that beneficiaries retain their freedom of choice of providers under the MSSP, we are concerned that ACOs might try to control costs by delaying referrals to specialists. Such delays could be extremely harmful to the beneficiaries' health, but the costs of postponing diagnoses and treatments might not be captured during the three-year agreement period. To promote the highest quality care from the most appropriate physicians, we recommend that CMS work with stakeholders to create and adopt measures for timely referrals to specialists.

III. CMS should require ACOs to include specialists in the groups that are responsible for selecting medical practice guidelines

Finally, CMS proposes to require each ACO to "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, [and] lower growth in expenditures."[12] ACO participants and providers/suppliers would be required to "agree to comply with these guidelines and processes and to be subject to performance evaluations and potential remedial actions."[13] These guidelines and processes clearly will play a critical role in each ACO's efforts to ensure that all of its physicians, providers, and suppliers work together to provide quality care to its patients. It will be essential to include physicians with relevant expertise in the groups charged with selecting and implementing the guidelines. If primary care physicians are permitted to select guidelines without input from relevant specialists, the ACO could adopt guidelines that do not reflect appropriate standards of care for their patients. Accordingly, we recommend that CMS require each ACO to include relevant specialists in the development and implementation of these guidelines and processes.

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[9] Id.
[10] Id. at 19592.
[11] Id. at 19537.
[12] Id. at 19543.
[13] Id.

In conclusion, MDMA appreciates this opportunity to comment on the Proposed Rule, and we look forward to working with CMS as it implements the MSSP and other programs involving ACOs. If you have any questions about these comments, you may contact me at (202) 354-7171.

Sincerely,

Thomas C. Novelli
Vice President of Government Relations
Medical Device Manufacturers Association