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AdvaMed
Advanced Medical Technology Association

June 6, 2011

Donald M. Berwick, Administrator, Centers for Medicare & Medicaid Service
Daniel R. Levinson, Inspector General
Department of Health and Human Services
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, D.C. 20201

Re: Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center (CMS-1345-NC2); Notice with Comment Period.

Dear Dr. Berwick and Mr. Levinson:

I am writing on behalf of the Advanced Medical Technology Association (AdvaMed) to offer comments on the notice with comment period entitled "Medicare Program: Waiver Design in Connection with the Shared Savings Program and the Innovation Center," published in the *Federal Register* on April 7, 2011.1 AdvaMed greatly appreciates this opportunity to comment.

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. These products and services improve patient care quality and many improve efficiency by reducing the lengths of stay, allowing procedures to be performed in less intensive and less costly settings, providing early detection of disease and infections, improving the ability of providers to monitor care, among other benefits. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed provides comments below on the following: (I) the scope of the waivers; and (II) additional safeguards to improve quality of care and safeguard patient access.

1 76 Fed. Reg. 19655 (April 7, 2011).

I. Scope of the Waivers

While AdvaMed believes that Accountable Care Organizations (ACOs) hold promise for improving quality and efficiency of care, Medicare's ACO initiatives must be carefully constructed so they reach their potential while respecting an essential design feature—that they will be embedded within the Medicare fee-for-service program where beneficiaries typically have freedom of choice and access to any participating provider they choose. A large proportion of Medicare beneficiaries elect to be served by this program, and the Medicare Shared Savings Program (MSSP) has the potential to advance the three-part aim in this context, so long as safeguards are built into the program to protect patient access, quality of care, and to preserve independent physician-patient decision-making.

In contrast to managed care, fee-for-service affords beneficiaries more flexibility in choosing providers and seeking care without a plan affecting these decisions. To prevent inappropriate incentives from influencing clinical decisions in the fee-for-service Medicare program, Congress enacted several statutes, including the anti-kickback statute, the physician self-referral law, and the civil money penalty law. To permit ACOs to function effectively, the Affordable Care Act permits the Secretary to waive these statutes. AdvaMed believes that any such waivers should be carefully constructed, clearly stated, and carefully monitored to ensure that they achieve their purposes without eroding unnecessarily the protections against inappropriate incentives affecting clinical decisions provided by the underlying statutes.

In particular, AdvaMed has repeatedly emphasized that gainsharing programs, which would require waivers of the civil monetary penalty law (CMP) (sections 1128A(b)(1) and (2) of the Social Security Act), must be carefully designed in order to prevent patients from being put at risk from inappropriate incentives that influence clinical decisions, leading to stinting on care or otherwise inappropriate choices. In general, gainsharing is defined as "an arrangement in which a hospital gives physicians a percentage share of any reduction in the hospital's costs for patient care attributable in part to the physicians' efforts."[2]

To the extent that waivers of the anti-kickback statute, physician self-referral law and the CMP law are necessary, AdvaMed believes they should be narrowly targeted to their purpose. The general standard articulated in the notice, that these waivers be for activities "necessary for and directly related to" the operation of ACOs, appears to be a reasonable approach to the ACA provisions interpreted in the context of these underlying statutes.[3] AdvaMed believes, however, that the implications of this standard need to be more fully specified.

In particular, the scope of the waivers should relate to the source of the savings. Waivers under section 1899 should relate only to sharing savings that are captured by the Medicare program,

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[2] See OIG Special Advisory Bulletin, "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999).

[3] Section 1899 allows the Secretary to waive such requirements of section 1128A and 1128B and title XVIII of the Social Security Act "as may be necessary" to carry out the provisions of section 3022 of ACA (the Medicare Shared Savings Program).

not to providing incentives to generate savings that accrue to providers but that do not produce savings for Medicare. For example, some gainsharing initiatives have involved providing physicians with financial incentives for confining choices of particular devices for surgeries or other procedures to those on a preferred list (a practice known as "device standardization"). However, this practice generates savings within a diagnosis-related group or other payment bundle but does not create savings for Medicare that can be captured by the Medicare Shared Savings Program (MSSP). Consequently, such practices should not be permitted under waivers pursuant to section 1899.

AdvaMed recognizes that it may be difficult to draw clear lines in all instances. However, the critical element appears to be that the providers in the MSSP are paid standard Medicare fee-for-service rates. Thus, the only source of savings that should be considered directly related to the operation of an ACO can be achieved from team collaboration among ACO providers working together to streamline and coordinate processes of care and to better manage chronic disease, and not from stinting on care. An ACO's planned and actual distribution of savings should be scrutinized to ensure that savings paid to practitioners do not reflect participation in savings initiatives that financially benefit providers, but not the Medicare program.

Further, AdvaMed believes that it is critical that the agencies make fully clear what waivers are applicable to the MSSP and the Innovation Center. We have already noted tendencies among interested observers to believe that a broad array of gainsharing arrangements might be permissible. To avoid confusion among ACO applicants and participants and to forestall the conclusion that the ACO program provides a "back-door" way of securing approval for gainsharing arrangements that would not be approved otherwise, we urge the agencies to be clear and detailed in their descriptions of what kinds of arrangements are included in waivers and what are not, both in subsequent notices in the Federal Register, in any other guidance document(s), and in enforcement processes.

Furthermore, AdvaMed supports the bright line drawn in the proposed waivers, clarifying that the scope of arrangements covered by the waiver would not include arrangements between the ACO and third parties, or between or among the ACO, ACO participants, and ACO providers/suppliers that are not necessary for and directly related to the MSSP. Extending the waiver more broadly would be inconsistent with the ACA requirement that the Secretary only waive the law as may be necessary to carry out the Medicare Shared Savings Program. There are many existing and potential arrangements between hospitals and physicians that are unrelated to the Shared Savings Program's mission of improving quality and coordination of care. The following are three examples:

> (i) hospitals subsidizing physician office leases or administrative support staff expenses in exchange for physician use of the lowest cost device without regard to quality or individual patient needs;
>
> (ii) hospitals and physicians entering into co-management agreements or other joint venture arrangements that enable profit-sharing, in exchange for physician use of the lowest cost device without regard to quality or individual patient needs; and

(iii) hospital use of products purchased from physician-owned distributors, without regard to quality or individual patient needs.

These examples are indicative of the legal and patient care risks attendant in expanding the waiver authority. These legally problematic arrangements serve only to reduce cost to the detriment of patient care. There are many ways health care entities and physicians could potentially structure their financial relationships to enhance their payments without regard to quality improvement and coordination of care. Expanding the waiver authority would open the door to protecting activity that presents a significant risk of patient abuse.

II. Additional Safeguards: Improving Quality of Care and Protecting Patient Access

AdvaMed has longstanding concerns with initiatives or arrangements that potentially threaten quality of care and patient access. While ACOs hold the promise of transforming the payment system from one that rewards based on volume to one that rewards based on quality and efficiency, there is a risk that the pendulum could swing too far and lead some providers and professionals to limit patient care, use less effective (and inappropriate) products or methods of treatment, or delay or deny access to appropriate care in order to achieve greater shared savings.

AdvaMed's comments in response to CMS's MSSP proposed rule noted that the 65 proposed quality measures are necessary, but limited in scope and insufficient to ensure that quality of care is not compromised. AdvaMed is concerned that without significantly stronger safeguards to minimize incentives for reducing costs at the expense of quality, patient care will suffer.

AdvaMed has recommended that the following key safeguards be integrated into the final MSSP regulations. If, however, CMS does not incorporate these safeguards into the MSSP final rule, AdvaMed recommends that OIG and CMS integrate as many as possible of these additional safeguards as conditions of the fraud and abuse law waivers. These recommended safeguards fall into two categories: (1) stronger oversight and monitoring; and (2) protecting patient access to needed care.

1. Stronger Oversight and Monitoring

AdvaMed supports CMS's plans to monitor care provided by ACOs, as enumerated in the proposed rule, and specifically a proposal to include among CMS monitoring activities analysis of specific financial and quality measurement data, site visits, and audits. However, the MSSP regulations can and should include additional and stronger safeguards, and more rigorous oversight of patient care in the ACO model, both to encourage beneficiary engagement with the ACO model as well as to provide stronger checks on patient care experiences to detect whether there has been an effect on access to the treatments that are most appropriate for individual patient needs. To address these concerns, AdvaMed has recommended that CMS incorporate the following into the final MSSP regulations.

Recommendation #1a: Implement an Independent Clinical Care Monitoring Program - AdvaMed recommends that a comprehensive independent monitoring program be developed to provide the impartial analysis needed to assure beneficiaries that the model

will improve their care outcomes. An independent monitor should be tasked with providing an in-depth medical review/clinical audit of beneficiaries in ACOs, comparing their care and health outcomes to professionally recognized standards. This evaluation would include analysis of patient medical records (not simply claims data), and a comparison of ACO and non-ACO beneficiaries' utilization of specific services, including a review of referrals to medical specialists and the inappropriate substitution of Part D prescription drugs, which are not included in the calculation of the benchmark for Part A or Part B treatments, for services which are included in the benchmark.[4] AdvaMed recommends that the independent monitor's first report be available to the public no later than 3 months after the close of the first year's reporting period. (Recommended amendment to §425.12)

The independent monitor should also survey ACO participating beneficiaries and providers. Provider surveys should include their assessment of the availability of products and services and changes in practice that have been implemented under the ACO model. Similarly, beneficiaries should be independently surveyed regarding their assessment of the care they received and the results should be compared to survey results from beneficiaries receiving care through the traditional fee-for-service Medicare program. These results should also be made public. This monitoring program could be implemented through a CMS-appointed independent monitor for each ACO or alternatively by using one monitor for several ACOs in the same general area. (Recommended amendment to §425.12)

Recommendation #1b: Require New Safeguards in ACO Applications and Clinical Expertise in Approving Each ACO Plan--ACO applications should include statements describing 1) detailed plans for preserving patient and physician clinical decision-making; 2) plans for fully informing patients about their full range of treatment options, including medical advances and emerging technologies, and those available only outside the ACO; and 3) processes for ensuring beneficiary access to specialists' care and advances in medical treatments and emerging technologies, including participation in clinical trials. In addition, CMS's evaluation of ACO applications for meeting these requirements and others proposed by CMS to be included in the final rule should include a review by, and input from, clinical experts. (Recommended amendment to §425.5(d)(15))

Recommendation #1c: Report on How ACO Achieved Shared Savings — The proposed rule requires that the ACO make a written request to CMS for payment of shared savings (or acknowledge the amount of shared losses) in a document that certifies compliance

[4]. For an example of potential Part A or B substitution to Part D, see the discussion of heart rhythm medicines and radiofrequency ablation in AHRQ's publication entitled, "Radiofrequency Ablation for Atrial Fibrillation, A Guide for Adults" available at the following link: http://effectivehealthcare.ahrq.gov/ehc/products/51/348/RFA%20consumer.pdf

with program requirements as well as the accuracy, completeness, and truthfulness of any information submitted to CMS. Such request should include a complete description of how the ACO achieved savings (or incurred losses). This description should include data analysis on utilization of specific categories of services, referrals to specialists, utilization of new treatments and technologies, lengths of stay in facilities, changes in health status of patients, etc. The ACO's description of how it achieved shared savings (losses) should be made available to the public along with the release of the independent monitor's public report. (Recommended amendment to §425.5(d)(12))

2. Protecting Patient Access to Needed Care

While ACOs hold promise for improving the quality and efficiency of care, new incentives embedded in the ACO design could have the inadvertent effect of compromising patient access to the full array of treatment options. Medicare beneficiaries with conditions that require more expensive treatment options could be seeking care from providers who will have incentives to limit access in order to reduce costs and enhance the shared savings pool that would be available to them at the end of the year.

The ACO model, therefore, has significant implications for the care beneficiaries need and receive. Patients should be able to consider whether the model and its incentive structure are appropriate for their unique health care needs. Requiring that Medicare beneficiaries provide informed consent to receive care from an ACO participating provider is an appropriate step to ensure patient-centered care.

Recommendation #2a: Require Beneficiary Informed Consent through Notification and Acknowledgement--Medicare beneficiaries should be fully informed of the potential benefits and concerns associated with receiving care from ACO participating providers. Such information should be balanced and fully explain the opportunities for increased coordination of care and the implications of the incentive structure and rewards to participating providers. Beneficiaries should indicate annually that they have been fully informed of these benefits and concerns and are choosing to seek their care from a primary care physician and other providers who are participating in an ACO. The patient form should include a statement that the beneficiary is entitled to all Medicare covered Part A and B benefits outside the ACO, including services from specialty providers outside the ACO. In addition, the beneficiaries should receive clear information about two distinct decisions they must make about ACOs. First, whether they will see an ACO participating primary care physician and other providers or move to another primary care doctor and second, whether they will decline to share their identifiable claims data with their ACO-participating primary care physician or other ACO providers. (Recommended amendment to §425.6 and 425.19(d)(4))

Furthermore, financial incentives offered to ACO providers for reducing costs and sharing in savings should not interfere with their patient-centered clinical decision-making. Limiting the financial incentives offered to physicians is one way to limit the adverse impact on patient care that can result from financial incentives to limit items and services. Payment on a per capita

basis, or other rational basis tied to quality of care mitigates an individual physician's incentive to generate disproportionate cost savings by stinting on care in an effort to increase their personal level of shared savings. While some may argue that ACOs need to be given maximum flexibility in deciding how to allocate shared savings within the ACO, AdvaMed recommendeds that Medicare's ACO regulations include a number of ground rules to limit incentives to stint on patient care.

> ***Recommendation #2b: Distribute Savings Based Solely on Team Effort or Other Rational Basis and Quality***— ACOs should be required to distribute shared savings among participating physicians and other health care professionals on an equal per capita or other rational basis that would discourage physicians from generating disproportionate cost savings by stinting on care in an effort to increase their personal level of shared savings. This recommendation is consistent with OIG Advisory Opinions on similar matters. Moreover, it is consistent with the general concept behind ACOs—savings can be achieved from team collaboration among ACO providers working together to streamline and coordinate processes of care and to better manage chronic disease, and not from reducing or limiting appropriate care. To the extent that CMS allows providers to be rewarded differentially for their performance in an ACO, it should be done strictly on the basis of performance on the designated quality standards and providing superior care. (Recommended amendment to §425.5(d)(11))

In the proposed Notice, the OIG and CMS suggest that there is heightened concern:

> "where ACO participants and/or ACO providers/suppliers may individually bear risk for the cost of items and services furnished to ACO beneficiaries. For example, we are interested in whether such waivers should extend only to compensation that places referring parties at risk for achieving the quality and performance metrics under the Medicare Shared Savings Program."[5]

AdvaMed agrees that there is heightened concern where individual participants bear risk based on costs that they individually incur or save. This would be the case in either the one-sided risk model, or the two-sided risk model because the one-sided rmodel becomes two-sided in the third year. Moreover, even if an ACO were one-sided only for all three (or more) years, there are clear incentives to limit items and services by rewarding physicians and other participants based on cost savings. Per capita distribution of savings, with differential rewards based on performance on designated quality standards, will help to attenuate the financial incentive to stint on care.

* * *

As stated above, if these recommendations are not adopted by CMS as part of the MSSP final rule, AdvaMed recommends that OIG and CMS include as many as possible of the safeguards

[5] 76 Fed. Reg. at 19660.

outlined in the above recommendations as prerequisites to granting fraud and abuse law waivers for ACOs that wish to participate in the MSSP.

Thus, for example, OIG should consider developing its own independent clinical care monitoring program, conditioning waiver of the anti-kickback statute and gainsharing CMP on findings by an independent monitor that patient care (both quality of care and access to care) was not compromised by the ACO. CMS and OIG could also require that additional information be submitted with the MSSP applications and that the ACOs report on, and make public, how they achieved shared savings. Furthermore, AdvaMed urges the OIG and CMS to ensure that beneficiaries are fully informed about the potential impact of the ACO on their care, and that shared savings be distributed equally among physicians (with differential rewards based on performance against quality standards).

If OIG and CMS do not incorporate these safeguards as conditions of waiver, AdvaMed recommends that OIG conduct periodic clinically-based evaluations and audits to ensure that for Medicare beneficiaries affected by the MSSP, quality of care and access to care are not compromised. The MSSP is intended to enhance coordination of care and to improve quality of care, while reducing overall cost. The potential unintended consequences, however, could be damaging for affected Medicare beneficiaries. It is well within the OIG's mission to investigate, audit and evaluate ACOs to determine whether any patient or program abuse results from implementation of the MSSP.

Finally, OIG and CMS have asked for public comments on the separate waiver authority at section 1115A(d)(1) of the Social Security Act in relation to addressing similar issues for demonstrations and pilots run by the Center for Medicare and Medicaid Innovation ("Innovation Center"). In light of the broad array of demonstrations and pilots that may be undertaken by the Innovation Center, it is critical that OIG and CMS evaluate each project individually to determine the appropriate scope of activity for which the fraud and abuse laws should be waived, ensuring that there is no risk of patient and program abuse. For any ACO or other hospital-physician arrangement, AdvaMed recommends that CMS and OIG incorporate the above-mentioned safeguards as conditions of waiver.

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AdvaMed appreciates the opportunity to provide comments on the CMS and OIG's proposed waiver designs in connection with the MSSP and the Innovation Center. Should you have any questions, please contact me at (202) 434-7203.

Sincerely,

Ann-Marie Lynch
Executive Vice President
Payment and Health Care Delivery Policy