June 29, 2012

Via Electronic Mail
United States Senate
Committee on Finance
Dirksen Senate Office Building
Washington, DC 20510-6200

Re: May 2, 2012 Program Integrity White Paper Request

Dear Senators Baucus and Hatch:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to comment on the Senate Finance Committee’s request to submit ideas for improving program integrity efforts in the Medicare and Medicaid programs. While much has been done over the past several years to reduce incidents of fraud, waste, and abuse there is still room for improvement.

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. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed recommends that two areas be considered for program integrity initiatives to ensure Medicare/Medicaid beneficiary access to appropriate care: (1) health care delivery and payment reform models, such as ACOs and bundled payment programs, in which financial incentives among providers are aligned to reduce spending growth, improve patient quality of care, and increase provider revenues/incomes, and (2) the role that physician-owned supply chain companies/physician-owned distributorships play in increasing Medicare and Medicaid utilization of specific procedures and spending for these procedures. Our comments below address these two issues.
**ACOs and Bundled Payment Programs**

AdvaMed recognizes the promise that ACOs and bundled payment programs hold for encouraging greater coordination and collaboration among providers to improve outcomes for patients. However, we are concerned that the significant financial incentives for reducing costs that are available to practitioners under these new delivery reform models can discourage providers from using innovative treatments and diagnostics that may bring value to patients and to the health care system over the longer term. The result can mean reduced patient access to technologies that are beneficial for their treatment and less positive health care outcomes. We are also concerned that these programs could result in stunting on care, cherry picking patients, and denying access to reasonable and necessary care and/or care recommended by practice guidelines.

In an effort to ensure that the objectives of the ACO and bundled payment programs are met without compromising patient access to necessary and appropriate care, AdvaMed recommends that all such programs be monitored closely to make sure that they are promoting the best care for Medicare beneficiaries. CMS should provide for strong oversight of the ACO and bundled payment programs, including use of an outside independent monitor to do an in-depth medical review or clinical audit of beneficiaries in both program types, comparing their care and health outcomes to professionally recognized standards. A comprehensive independent, clinically rigorous, monitoring program would provide the impartial analysis needed to assure beneficiaries that the models will improve care outcomes.

AdvaMed recommends that the independent monitor’s evaluation include a comparison of beneficiary utilization of specific services, referrals to medical specialists, and analysis of patient medical records (not simply claims data). The evaluation should include both beneficiaries who receive their care from providers who are participating in an ACO/bundled payment initiative and beneficiaries who are not part of an ACO or bundling initiative. The independent monitor should also survey 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 both models. 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. The survey should also assess beneficiary input into decisions related to their health care and the level of participation in ACO governance by the designated beneficiary representative(s). All survey results should be made public.

AdvaMed also believes that ACO and bundled payment programs should operate with a high level of transparency. Beneficiaries that participate in either ACO or bundled payment programs should be informed of this fact and have a means of advocating for the care and services that they need. Medicare beneficiaries should also be fully informed of the potential benefits and implications of new incentives under the ACO and bundled payment programs. This would discourage individual providers from stunting on care in an effort to increase their personal level of shared savings and would be consistent with
the overall program goals—a team effort to reduce costs through better systems of health care delivery.

**Physician-owned Supply Chain Companies/Physician-Owned Distributorships**

AdvaMed also has significant concerns regarding the operation and role of physician-owned supply chain companies/physician-owned distributorships. These entities may incentivize behavior that compromises beneficiary access to appropriate care while potentially inducing wasteful and abusive behavior.

AdvaMed strongly believes that the first duty of health care professionals is to act in the best interests of patients. AdvaMed recognizes that some health care collaborations with health care professionals and providers can serve the interests of patients; however, interactions between companies and health care professionals must be conducted in an ethical manner to ensure that medical decisions are based on the best interests of the patient. AdvaMed believes that collaborations between hospitals and Physician-owned Supply Chain Companies must be conducted in a *transparent* manner and they must comply with applicable laws, regulations and government guidance.

The emergence of companies with equity investments by physicians, who also generate major revenue for the companies, raises important legal and policy issues relating to the potential impact of these arrangements on clinical decisions by physicians. These entities include physician-owned manufacturers, distributors, and group purchasing organizations that sell devices to hospitals at which the physician-owners treat patients. Collaborations among physicians and device developers and manufacturers yield advances in medical technology while including safeguards to protect against fraud and abuse. By contrast, physician-owned supply chain companies/physician-owned distributorships may seek to leverage device purchasing into income generating opportunities for investing physicians. Both the Office of Inspector General of the Department of Health and Human Services (OIG), and the Centers for Medicare & Medicaid Services (CMS) have expressed legal and programmatic concerns with physician-owned entities.¹

In February 2008, OIG officials indicated in Congressional testimony that physician-owned distributorships and other physician-owned companies “raise substantial concerns that a physician’s return on investment from the venture may influence the physician’s choice of device.”²

¹ The OIG stated its concerns regarding physician-owned joint ventures, noting that “[t]hese subject joint ventures may be intended...to back up a stream of referrals from the physician investors and to compensate them directly for their referrals.” Special Fraud Alert. Issued in 1989 and re-issued in 1994. In addition, the OIG expressed concerns that hospital incentive programs “used to compensate physicians (directly or indirectly) for referring patients to the hospital” implicate the anti-kickback statute and cause conflicts of interest, overuse of services and referrals to less appropriate hospitals. 1994 Special Fraud Alert. See also, OIG Special Advisory Bulletin on Contractual Joint Ventures.

CMS has also been critical of these entities, and has considered amending its Stark physician self-referral regulations to address physician-owned distributors and similar entities more specifically. Discussing physician-owned distributors along with similar physician-owned entities, CMS has stated that these entities “serve little purpose other than providing physicians the opportunity to earn economic benefits in exchange for nothing more than ordering medical devices or other products that the physician-investors use on their own patients,” and that in many instances such physician-owned entities “would not satisfy the requirements of the exception for indirect compensation arrangements in [42 C.F.R.] § 411.357(p), and would, therefore, run afoul of the physician self-referral [Stark] statute.”

AdvaMed shares the concerns expressed by the OIG and CMS that at least some of these entities have the potential to create conflicts of interest between a physicians’ responsibility to act in the best interests of patients and their own equity interests. Such entities may compromise (or appear to compromise) the physician-patient relationship and could further serve to restrict patient access to the most appropriate advanced medical technologies.

Conclusion

AdvaMed supports the implementation of safeguards that protect Medicare beneficiaries from fraud, waste, and abuse and that improve the Medicare payment system. We appreciate the opportunity to comment on these important matters. Should you or your staff have any questions, please contact me at (202) 434-7203 or ALynch@AdvaMed.org.

Sincerely,

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

Cc: Sen. Tom Carper
    Sen. Tom Coburn
    Sen. Charles E. Grassley
    Sen. Ron Wyden

