September 5, 2013

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS Request for Public Comments on the Potential Release of Medicare Physician Data

Dear Administrator Tavenner,

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services’ (CMS) request for public comments on the potential release of Medicare physician data.¹

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. In addition, they often 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, and 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.

While AdvaMed does not take a position on the broader question of the release of physician Medicare reimbursement payments generally, we believe CMS is presented with a unique opportunity to develop and implement an important policy that would protect Medicare beneficiaries when they receive care from physicians who may earn significant financial incentives by participating in an accountable care organization (ACO) under the Medicare Shared Savings Program (MSSP), the Pioneer ACO or Advanced Payment ACO programs, or in bundled payment initiatives.

For the reasons discussed below, AdvaMed believes the Secretary of Health and Human Services (HHS) should publicly disclose shared savings or gainsharing amounts earned by physicians in

ACO programs and bundled payment initiatives. Specifically, we believe CMS should require ACOs (already required under 42 CFR § 425.308) and participants in the bundled payment initiatives to publicly disclose aggregated amounts of shared savings and Gainsharing rewards that the physicians participating in those programs receive. The ACOs and participants in the bundled payment initiatives should also release information about the methodology they use for distributing shared savings and Gainsharing rewards among participating physicians and other practitioners. Furthermore, CMS should publicly disclose, or require that ACOs or bundled payment initiatives publicly disclose, physician-specific information on the shared savings and gainsharing amounts that physicians receive as a result of their participation in the programs. AdvaMed does not take a position on the broader question of whether CMS should disclose personally-identifiable information on the total amount of Medicare payments made to a physician.

CMS’ request for comments asks for input on three specific questions. We respond to each one in turn below.

I. Background

In 1979, the United States District Court for the Middle District of Florida issued a permanent injunction which broadly prohibited the Secretary from disclosing “any list” of annual Medicare reimbursement amounts, “for any years,” if disclosing such information “would personally and individually identify providers of services under the Medicare program who are members of the recertified class.” On May 31, 2013, the U.S. District Court Middle District of Florida vacated the injunction, “conclude[ing] that vacatur of the 1979 FMA Injunction is appropriate, and ‘suitably tailored to the changed circumstance’ in this case [internal citation omitted].” With the injunction lifted, HHS is legally permitted to revise its policy on disclosing Medicare reimbursement payments to individual physicians in a manner that could identify individual physicians. The Department’s policy on the release of physician information has not been updated since 1980, when HHS concluded that “the public interest in the individually identified payment amounts is not sufficient to compel disclosure in view of the privacy interests of the physicians found compelling by the courts.”

II. Response to CMS Questions

1. Specific policies CMS should consider with respect to disclosure of individual physician payment data

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AdvaMed recommends CMS adopt and implement a policy of transparency and physician payment disclosure specifically applicable within ACO programs and any bundled payment initiatives. The ACO and bundling payment initiatives have the potential to encourage quality care and efficient health care delivery. However, AdvaMed is concerned that in an effort to incentivize care coordination, efficiency, and reduced costs under ACOs and bundled payment initiatives, ACOs and bundled payment providers may create unintended incentives for individual providers to reduce costs of care even if this is not in the best medical interest of the beneficiary who is assigned to the ACO or is included simply because the beneficiary’s physician chooses to participate in a bundled payment program.

With respect to the MSSP, for example, when HHS issued its MSSP Final Rule in November 2011, it concurrently issued an Interim Final Rule (IFC) describing the ACO Participation Waiver. Through the ACO participation waiver, the Department waived section 1899(f) of the Act, section 1877(a) of the Act (relating to the Physician Self-Referral Law), sections 1128A(b)(1) and (2) of the Act (relating to the Gainsharing Civil Monetary Penalty (CMP), and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute), with respect to an ACO and its participants as long as certain conditions described in the final rule are met. One condition is that “[t]he description of the arrangement is publicly disclosed at a time and in a place and manner established in guidance issued by the Secretary. Such public disclosure shall not include the financial or economic terms of the arrangement.”

Recognizing that there was inherent risk in the policy that the Department was introducing, HHS stated that “if we find that undesirable effects (for example, aberrant patterns of utilization) have occurred because of the waiver, we will revise this IFC to address those problems by narrowing the waivers.” HHS also stated that it is “exclud[ing] from the shared savings distributions waiver of the Gainsharing CMP situations in which a payment is made knowingly to reduce or limit medically necessary services to patients under the physician’s direct care.” HHS explained that

Knowing payments by a hospital to induce a physician to reduce or limit medically necessary care without providing acceptable alternative medically necessary care (for example, payments to discharge patients without regard to appropriate care transitions or payments to use a drug or device known to be clinically less effective) would not qualify for the waiver. We will interpret “medical necessity” consistent with Medicare program

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5 76 Fed. Reg. 68000-01 (Nov. 2, 2011). CMS also noted that “The third main safeguard included in these waivers is a transparency requirement that requires arrangements for which waiver protection is desired to be publicly disclosed. The public disclosure will include the description of the arrangement, but shall not include the financial or economic terms of the arrangement. Our decision to shield financial or economic terms from the public transparency requirement is premised, among other considerations, on potential antitrust implications. (We note that, while not subject to the public transparency requirement, the financial or economic terms of the arrangement are among the matters that must be documented pursuant to the documentation requirements of the waivers and made available to the Secretary upon request.)” 76 Fed. Reg. 68004.


7 76 Fed. Reg. at 68005.
rules and accepted standards of practice. We also note that distributions of shared savings payments also may be structured to fit in the other waivers.\textsuperscript{8}

AdvaMed is concerned that the MSSP Interim Final Rule and the waivers concurrently created are insufficient to protect beneficiaries from the unintended consequences that may result from arrangements where physicians are incentivized with personal financial rewards to reach savings in their care regimens. Similarly, in the case of bundled payment initiatives, where payment is set for a defined inpatient stay, or “episode of care,” and physicians may be “permitted to share gains arising from the providers’ care redesign efforts,” AdvaMed believes there are inadequate beneficiary safeguards in place.\textsuperscript{9}

Incentives for reducing costs have the potential to lead to stinting on care, denying needy specialty referrals or higher cost tests and interventions or selecting cheaper technologies, even when the specialty referrals or higher cost tests and interventions are the most appropriate treatment for the individual. Furthermore, the limited payment windows used to evaluate costs within the ACO and bundled payment initiatives provide significant disincentives to treat patients with interventions that demonstrate long-term value. This may lead to focus on short-term cost savings even when this is not in the best long-term interest of the patient.

One way to monitor for a connection between suspiciously high financial gains by individual physicians and the withholding of the most appropriate treatments and technologies due to cost would be to publicize the amount of shared savings or Gainsharing amounts that physicians receive as a result of their participation in an ACO or bundled payment initiative. This information could then be coupled with data on the treatments and technologies that the beneficiary who is assigned to the ACO or treated by the bundled payment provider receives. AdvaMed strongly urges CMS to create and implement policies that would allow for such disclosure and transparency that will protect Medicare beneficiaries and uphold quality in the Medicare program. To this end, AdvaMed recommends that CMS and individual ACOs and bundled payment initiatives make available to the public both aggregated data and individual physician shared savings and Gainsharing rewards received by practitioners participating in these programs.

Finally, AdvaMed, as well as the Office of Inspector General of HHS (OIG), have repeatedly raised concerns with the characteristics and operations of many Physician-Owned Distributors (PODs).\textsuperscript{10} PODs can also raise the possibility of improperly incentivized physician decision-making, and for that reason, OIG has labeled them “inherently suspect.”\textsuperscript{11} AdvaMed recommends that any disclosure of Medicare reimbursement information concerning an individual physician also note whether that physician has an ownership interest in a POD. CMS will already have access to much of this information through the disclosure requirements of applicable GPOs (including most PODs) under the Physician Payment Sunshine Act, which

\textsuperscript{8} 76 Fed. Reg. at 68005.
\textsuperscript{9} See, e.g. CMMI, Bundled Payments for Care Improvement (BPCI) Initiative: General Information, Episode 1, available at \url{http://innovation.cms.gov/initiatives/bundled-payments/}.
\textsuperscript{11} Special Fraud Alert: Physician-Owned Entities, Office of Inspector General, 2013.
passed as part of health care reform in 2010 in the ACA (and is further addressed below).\textsuperscript{12} For any physician ownership of a POD not captured by the Sunshine Act, AdvaMed recommends that CMS create and implement a policy of physician self-disclosure of POD ownership.

2. Weighing the Patient and Public Interest Against Physician Privacy Interest

In implementing a policy of physician payment disclosure and transparency, as described above, it is necessary to consider whether there is a physician privacy interest at stake in the Medicare reimbursement information, and whether such interest outweighs the patient and public interest in having access to the information. Physicians do have a privacy interest in their personal income. Shared savings or Gainsharing amounts, however, constitute only a portion of a physician’s total income. Disclosing this subset of information, therefore, does not breach a physician’s reasonable expectation that his total income should be a private matter.

Moreover, where reimbursement information is limited to shared savings and Gainsharing amounts earned from specific Medicare programs, such as ACOs and bundled payment initiatives, AdvaMed believes that even if there is some personal privacy interest remaining, such privacy interest is outweighed by the public’s interest in safeguarding the safety of beneficiaries in these programs. These programs have vulnerabilities embedded in their design that put beneficiaries’ safety and care at risk and must be counterbalanced by Agency safeguards, such as transparency and disclosure.

Physicians may argue that the values publicized as shared savings or Gainsharing amounts could be taken out of context and harm their personal or professional reputation. Congress has addressed a similar argument, however, in the context of the Physician Payment Sunshine Act. Under the Sunshine Act, annual payments or transfers of value provided to physicians or teaching hospitals by applicable drug and device manufacturers must be reported annually to the Secretary, who will then make these data public. The Sunshine Act also requires manufacturers, GPOs, and most PODs to report the nature and value of any physicians’ ownership in the entity. In passing the Sunshine Act, Congress determined that information that might indicate inappropriate financial inducements should be disclosed and the public interest in disclosure outweighed privacy concerns.\textsuperscript{13}

In sum, patients have a great interest in knowing the financial incentives provided to their physicians, and knowing the shared savings or Gainsharing amounts that their physicians have earned as a direct result. Knowing the specific amounts of physician shared savings and Gainsharing amounts will inform Medicare beneficiaries and help deter physicians from stinting on beneficiary care (e.g. withholding or not utilizing interventions known to be clinically effective) in order to benefit financially. Furthermore, if physicians know the data will be made public, they could be deterred from becoming involved in improper practices at all. Finally,\textsuperscript{12}

\textsuperscript{12} See section 1128G of the Social Security Act, as added by section 6002 of the ACA.

\textsuperscript{13} See also, CMS, Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests; Final Rule, 78 Fed. Reg. at 9459 (Feb. 8, 2013). (stating that “We recognize that disclosure alone is not sufficient to differentiate beneficial financial relationships from those that create conflict of interests or are otherwise improper.... However, transparency will shed light on the nature and extent of relationships, and will hopefully discourage the development of inappropriate relationships and help prevent the increased and potentially unnecessary health care costs that can arise from such conflicts.”)
knowing that physician shared savings and Gainsharing amounts will be publically available will also keep CMS accountable to fulfilling its responsibility to identify provider outliers and to target more effectively the agency’s program monitoring activities for assessing a program’s performance.

For these reasons, AdvaMed strongly believes that the patient interest in having access to physician reimbursement data in the form of shared savings and Gainsharing amounts outweighs physician privacy interest in such data. While physicians may argue that they have privacy interest in the financial information itself, in weighing this privacy interest against patient interest in disclosure of Medicare payment information, including physician-identifiable reimbursement data, AdvaMed believes protecting Medicare beneficiaries is greater.

3. **Form in which CMS Should release information about individual physician payment**

AdvaMed believes the Secretary of Health and Human Services (HHS) should publicly disclose shared savings or gainsharing amounts earned by physicians in the MSSP and bundled payment initiatives. Specifically, we believe CMS should require ACOs and participants in the bundled payment initiatives to publicly disclose aggregated amounts of shared savings and Gainsharing rewards that the physicians participating in those programs receive. The ACOs and participants in the bundled payment initiatives should also release information about the methodology they use for distributing shared savings and Gainsharing rewards among participating physicians. CMS should also publicly disclose, or require that ACOs or bundled payment initiatives publicly disclose, physician-specific information on the shared savings and gainsharing amounts that physicians receive as a result of their participation in the programs. This information should at a minimum be posted on CMS and ACO and bundled payment participant websites.

With respect to the disclosure of individual physicians’ involvement with a POD, AdvaMed recommends that CMS include a notation or asterisk next to each individual physician’s name to signify that physician’s POD ownership.

**III. Conclusion**

Again, thank you for the opportunity to comment on this important matter regarding updating the Agency’s policy on the release of physician Medicare payment data. Should you have any questions or if we can be of any assistance, please do not hesitate to contact me at rprice@advamed.org or 202-434-7227