July 12, 2011

Via Email and United States Mail

Donald M. Berwick, M.D., Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave, S.W.
Washington, D.C. 20201

Re: AdvaMed Comments on Implementation of Sunshine Provisions
Of the Affordable Care Act

Dear Administrator Berwick:

On behalf of the members of the Advanced Medical Technology Association (“AdvaMed”), we thank you for convening the March 24, 2011 Open Door Forum to collect stakeholder comments on implementation of Section 6002 of the Affordable Care Act (the “Sunshine Provisions”). We were pleased to learn during the Open Door Forum that CMS will develop regulatory guidance to ensure effective implementation through a public notice and comment process. We look forward to working with CMS through that process. Also, thank you for meeting with AdvaMed representatives on April 12, 2011. The interactive dialogue was helpful in further developing our policy recommendations.

Further to our verbal comments offered during the Open Door Forum and our meeting of April 12, we submit the following recommendations for CMS consideration.

Background

AdvaMed is the world’s largest trade association of medical device manufacturers who produce the medical technologies that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed represents approximately 370 manufacturers of medical devices, diagnostics, and health information systems, ranging from the largest to the smallest medical technology innovators and companies. With over $136 billion in domestic sales in 2008, AdvaMed members manufacture roughly 60 percent of U.S. sales of medical technology.

AdvaMed supports and has proactively embraced appropriate disclosure of relationships between medical technology companies and physicians. We and our member companies recognize that strong ethical standards are critical to ensuring appropriate collaboration between
the medical device industry and health care professionals to produce the world’s most advanced medical technologies. AdvaMed and our member companies take very seriously our responsibility to ensure ethical interactions with our physician partners. We recognize that adherence to ethical standards is essential to the industry’s ability to continue its collaboration with health care professionals. That is why AdvaMed developed a Code of Ethics on Interactions with Health Care Professionals1 (“AdvaMed Code” or “Code”) to distinguish interactions that result in bona fide contributions to the advancement of medical technology, from interactions that may inappropriately influence medical decision-making. AdvaMed has taken aggressive steps to educate the industry and health care professionals about the Code, ethical interactions, and compliance.

The medical technology industry is fueled by intense competition and the innovative energy of our member companies – firms that drive very rapid innovation cycles among products, in many cases leading new product iterations every 18 months. Our constant innovation leads to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible.

Physicians and teaching hospitals are partners in many aspects of innovation. They are often the inventors of new devices, and it is critical that our industry work closely with them to move their innovative ideas from concept to reality. Physicians make valuable recommendations on how to improve existing devices and provide ongoing consulting to provide expert technical assistance and feedback to companies in the development and refinement of those improvements. In short, physician expertise, feedback, and experience are critical to ongoing advances and innovations in medical technology, and the Sunshine provisions must be implemented in a manner that does not discourage physicians from participating in bona fide collaborations that fuel medical device innovation.

In addition, device companies forge important training arrangements with physicians and teaching hospitals, essential for the safe and effective use of medical devices. How well a medical device works depends, in large part, on the skill and training of the physician utilizing the technology. In fact, the FDA often requires device manufacturers to provide product specific education and training to physicians as a condition of FDA clearance. The technique-specific nature of devices also makes physician involvement crucial to the training and education required after market approval, as specific techniques often need to be taught, and physician operators are best suited to provide this training to their fellow physicians. Some training on medical technologies requires travel to central facilities that can accommodate large medical technologies or to specialized training facilities, such as simulated operating rooms.

Physician and teaching hospital innovation and collaboration with the device industry have led to groundbreaking advances in patient care that benefit millions of American patients. These innovations have helped fuel a robust, competitive U.S. medical technology industry that is the global leader. We applaud President Obama’s focus on innovation as the key to our nation’s economic future, and our industry stands ready to play a key role. The Sunshine provisions

1 Available at: http://www.advamed.org/MemberPortal/About/code/
should be implemented in a manner that serves the legislative intent to provide patients with clear, meaningful information concerning industry relationships, but implementation should not discourage beneficial interactions critical to the development and safe and effective use of innovative medical technologies. For this reason, in our comments below, we offer recommendations in certain areas to provide clear rules and definitions to facilitate a common approach by manufacturers and to ensure the data is meaningful.

1. **Covered Recipients**

   **A. “Teaching Hospital”**

   AdvaMed recommends that CMS define “teaching hospitals” based on the definition set forth in 42 C.F.R. § 415.152:

   “Teaching hospital means a hospital engaged in an approved GME residency program in medicine, osteopathy, dentistry, or podiatry.”

   *Approved graduate medical education (GME) program* means one of the following:

   (1) A residency program approved by the Accreditation Council for Graduate Medical Education of the American Medical Association, by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association, by the Commission on Dental Accreditation of the American Dental Association, or by the Council on Podiatric Medicine Education of the American Podiatric Medical Association. (2) A program otherwise recognized as an “approved medical residency program” under §413.75(b) of this chapter.”

To effectively implement this provision, we recommend that CMS publish annually a list of teaching hospitals that CMS has determined meet the criteria of this definition. Further, we recommend that CMS publish the unique identification numbers for those teaching hospitals that companies must utilize in their reporting. An annual list of teaching hospitals and unique identifiers from CMS will ensure uniformity and accuracy of reporting and that the public database contains information clear to patients. A single national list of covered recipients is necessary to ensure efficient administration of the new database by CMS, by establishing certainty among the many stakeholders, and will help CMS avoid numerous downstream administrative and management burdens associated with the receipt, management and posting of separately identified covered recipients. Such a list will also make it more efficient for companies to comply. Moreover, teaching hospitals may hold multiple provider and supplier numbers, and use of a single CMS-assigned number would facilitate accurate reporting.
Further, we recommend that CMS publish the list no later than October 1st of each year to facilitate integration of this key data into company tracking systems (and validate those systems) before the next calendar year reporting begins. Of course the identification of covered recipients will present ongoing maintenance and administrative concerns, as new covered recipients are licensed or accredited, and other covered recipients no longer qualify under the technical definitions. For this reason, AdvaMed recommends that CMS establish an administrable and regular process to update the list (e.g., quarterly), and allow companies a reasonable period after inclusion on the list to incorporate new covered recipients into their tracking systems.

B. “Physician”

Similar to the approach described above, AdvaMed recommends that CMS publish annually a list of the specific individuals that CMS has determined meet the definition of “physician” under Section 1861(r). This statutory reference includes a wide variety of disciplines (e.g., MD, D.O., DMD, DDS, DPM, optometrist, chiropractor) furnishing professional services within the scope of licensure and covered under Medicare and state health care programs. CMS should also publish the unique identification numbers for those individuals meeting the definition of “physician” that companies must utilize in reporting, as some physicians may not have an NPI number or may have multiple NPI numbers. As noted in the section above, the list should be published no later than October 1st of each year so that companies can integrate the information into tracking systems and have time to validate those systems before the next calendar year reporting begins.

Finally, we wish to emphasize that medical device innovation occurs on a global scale. That is, some medical technology arrangements span national borders, and the treatment of global collaborations presents significant complexities and administrative concerns for CMS and industry alike. To develop an administrable approach presenting meaningful data to patients, we suggest that for any covered recipient listed on the national CMS established list described above, CMS should require companies to report transfers of value only for physicians who currently practice in the U.S. and who receive transfers of value for activities that occur within the U.S.
C. “At the Request of or Designated on Behalf of”

This legislative text is likely to present implementation uncertainties and inconsistencies and, for that reason, is particularly in need of clarification by CMS. Where possible, CMS should be guided by federal income tax policy and treatment to facilitate a consistent treatment of this broad category of arrangements. That is, where a transfer of value is reportable as gross income to a covered recipient, it should qualify for reporting under the sunshine provisions.\(^2\)

Based on this approach, CMS should provide guidance that “on behalf of” occurs in the following circumstances:

a) Under the doctrines of constructive receipt, assignment of income, and economic benefit, a service provider may be taxed currently on a particular income because the service provider has discretion over the timing of the receipt and/or form of the benefit. Thus, when the physician requests that his/her payment is made to a specific charity of the physician’s choice, that payment should be reported as a payment to the physician.\(^3\) CMS should require that the payment record reflect that the physician directed the payment to a specific charity so it is clear to the public that the physician did not personally receive the funds. In this case, the physician would be issued a 1099 by the manufacturer.

By contrast, no report should be required when a payment is instead made to a charity that the manufacturer has selected, provided that the physician has waived his/her right to the fees in writing in advance of the services being performed and has no control over the choice of charity. This type of donation should not be reportable because it is of no benefit to the physician, the physician has completely waived his/her right to the income, and the charity was not selected by the physician. In this case, the physician would not receive a 1099 from the manufacturer.

b) In the case where a physician requests that the payment be made to another person or entity such as his/her private practice or consulting business, this payment should be considered as being made “on behalf of” the physician and should be reported as further described below.

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\(^2\)See generally Lucas v. Earl, 281 U.S. 111 (1930) (holding that a taxpayer who possesses a current or future right to income cannot shift the tax on such income by transferring the right to receive the income to another taxpayer).

Absent this interpretation, it would be altogether too easy for a physician to simply request that a payment owed be directed to the physicians’ private LLC or small practice group as opposed to the physician him/herself to prevent the payment from being reportable under Sunshine. In order to avoid such an outcome, we recommend that when a payment is not made directly to the physician, the information to be reported should include: a) the amount of money paid; b) the name of the physician who performed the work; and c) the entity which received payment on behalf of the physician.

c) By contrast, in cases where a manufacturer hires an entity, not the physician, to perform work without specifying that any particular HCP conduct the work, the payment should be reported only as paid to the entity to the extent required by the legislation because there is no direct financial relationship between the physician and the manufacturer in this case.

d) In the case of a clinical trial, when a physician payment is bundled together with an overall payment made to an institution, only the total payment to the institution would be reported to the extent required by the legislation. The reason for this is that clinical trial payments cover a broad range of services made by an institution well beyond physician services. Such services include nursing time, lab fees, patient care, medical supplies, statistician services, etc. Further, it is the institution, not the manufacturer, who determines how much to pay the physician. The payment to the physician is often one small component of an overall payment made to an institution.

D. Physician-owned distributors

The emergence of companies with equity investments by physicians, who are also major revenue generators for the companies, raises important legal and policy issues relating to the potential effect 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.

As opposed to the collaborations among physicians and industry, which yield advances in medical technology, these arrangements instead seek to leverage device purchasing into income generating opportunities for investing physicians. AdvaMed is concerned that at least some of these entities for which physicians generate substantial revenues have the potential to create conflicts of interest between physicians’ responsibility to provide the best care and physicians’ equity interests which 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.
Moreover, five U.S. Senators recently called for an investigation into physician owned distributors, citing concerns with the underlying incentives and overall legality of these arrangements. We support the Senators’ recommendation that CMS include physician owned distributors within the scope of the Sunshine legislation.4

The HHS Office of the Inspector General stated in correspondence to AdvaMed5 that these arrangements should be closely scrutinized under the fraud and abuse laws. Given the intent of the Sunshine Provisions to provide patients with clear information about all such relationships, we believe the legislative text can and should be interpreted to apply to the distributor model of these physician-owned entities.

While the Sunshine Provisions include express reporting obligations for two of these corporate models, CMS should issue guidance clarifying that physician-owned distributors are included in the scope of those entities that are required to comply with the reporting requirements.

The Sunshine Provisions require reporting of certain transfers for physician owned entities. These entities include “Applicable Manufacturers” and “Applicable GPOs.” The Sunshine Provision defines Applicable GPO as follows:

The term ‘applicable group purchasing organization’ means a group purchasing organization (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

The plain language of the statute delegates to the Secretary the authority to define the term GPO. Specifically, the phrase “as defined by the Secretary” grants the Secretary the authority to determine the meaning of GPOs as he or she deems appropriate for the purposes of the Sunshine Provisions.

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4 See Senate Committee on Finance Letter to Donald Berwick, M.D., Admin’r, Ctrs for Medicare and Medicaid Services (June 9, 2011) [http://finance.senate.gov/newsroom/ranking/release/?id=126c415e-f1a3-41e9-ab49-665a71188f1c].

2. Payments and Other Transfers of Value

A. Education and training; technical support

AdvaMed suggests that CMS consider defining a grant as funds transferred to a covered recipient in support of bona fide independent educational activities. This definition is consistent with the appropriate support of third party educational conferences under Section IV of AdvaMed’s Code of Ethics. Companies should not be required to impute a value to a training or education program, technical/case support, information on reimbursement, or report overhead, educational materials or supplies utilized in an education or training setting, including protective gear. Reporting should be limited to tangible and material support to covered recipients such as travel, food, and hospitality.

During our April 12th meeting, CMS inquired as to whether it would be possible to require companies to report the duration of each training program. Our member companies indicate that reporting systems are typically set up to track and capture dollar amounts associated with transfers of value, and not the duration of the education and training programs provided. In addition, reporting the duration of education and training would not add meaningful information to patients about the quality or importance of the program, as programs vary depending upon the device that is the subject of the training and the level of training involved (i.e. basic vs. more advanced training).

B. Reporting payments for activities that fall into more than one category

As a threshold point, to avoid situations where a transfer of value could be attributed to multiple categories, we propose CMS provide a limited number of categories with very clear definitions understandable to manufacturers and that provide the context of the transfer of value to consumers. CMS must avoid the situation that occurred with Massachusetts disclosure reporting pursuant to the 2009 Massachusetts Pharmaceutical and Medical Device Code of Conduct legislation where payments were categorized inconsistently causing concern by physicians and potential misunderstanding by consumers. There should not be overlap between categories and there should not be a hierarchy of categories (categories and subcategories) because that is most often where overlap and ambiguity occurs.

In some cases, a transfer of value to a covered recipient could be attributed to more than one reportable category outlined in the law (e.g. a two-day training program where travel, lodging, and meals are all included; a consulting contract that includes food and travel for meeting with company engineers that are working on the product development team).
In such cases, CMS should allow companies flexibility to segregate expenses into various categories or to report transfers of value under a single category that represents the dominant purpose for the transfer of value. For example, if the dominant purpose of the payment was for consultant work on an IDE protocol, then the company may report all transfers of value related to that rather than fragmenting into individual components. 6 AdvaMed suggests that consolidated reporting based on the dominant purpose should be at the election of the manufacturer, which may submit additional context relative to such transfers of value in the annual transparency reports to explain the nature of the arrangement.

C. Payments for services available to the general public

CMS should not require reporting of payments to physicians or teaching hospitals for commodity purchases at fair market value. For example, if a manufacturer rents a room (at established rates applicable to all outside parties, regardless of industry) at a hospital for purposes of conducting a training and education event at the hospital, that should not be reportable.

D. Payments for services required and provided by a covered recipient.

To avoid any confusion presented by ministerial business transactions, we recommend that CMS should not require reporting of payments for administrative services provided to the reporting company by the covered recipient, such as professional services (drug tests, vaccinations, health & wellness fairs, etc.), vendor credentialing (including credentialing required by the institution), online RFQ fees, administrative fees, and other vendor fees required by the institution.

E. Definition of “honoraria”

Honoraria are a subset of consulting arrangements and companies therefore should have flexibility to report these payments as “consulting services.” Absent this flexibility, CMS should provide a clear definition of “honoraria” to distinguish “honoraria” from other categories of payments (such as consulting).

F. Timing of reporting of consultant payments

For consultant contracts in which covered recipients perform many services over an extended period of time, CMS should require companies to report a payment to that covered recipient on the payment date (rather than on the date the covered recipient performs each service pursuant to the contract). It is often the case that payment is made after the provision of services, based upon proof of service documentation. In addition, often there is not a specific, single date upon which services are performed; services are frequently performed over several months or even across calendar years.

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6 Similarly, in the case of consultant travel, an itinerary might include multiple legs, attributable to different purposes.
G. Identifying payments that are related to a specific device or medical supply

In many cases, relationships between medical technology companies and covered recipients may involve multi-component product systems, or products with related product components, tools or accessories. For example, companies may provide education and training on multiple products as part of a single training program. Moreover, in the medical device and diagnostics industry, the specific brand name of a product is often not recognizable or meaningful to the consumer. In the case of a reportable activity that is related to a specific technology, CMS should allow companies to report according to a primary product group or therapy area, rather than based on the individual component product. For example, a heart lung machine must also be used with extensive catheter tubing, filters, and other accessories. The primary product, however, is the heart lung machine so payments should be reported in conjunction with that product only in order to avoid duplicate reporting and confusion. This will ease the reporting burden while providing clearer and more accurate information to patients.

H. Secretarial discretion to require reporting of “other categories of information the Secretary determines appropriate.”

Before adding additional categories, CMS should better define existing categories so that companies fully understand what is expected. Should CMS consider adding additional categories, it should provide companies with sufficient lead time to provide comment and adjust internal tracking systems to incorporate the new category.

I. Definition of an “in-kind service”

In general, CMS should require companies to report an “in-kind” service according to the existing categories that are specified in the legislation. Reimbursement, coverage and technical information furnished by companies to covered recipients should be exempted from reporting. As medical technologies have become increasingly complex, so have payor coverage and reimbursement policies. Consequently, a company may provide objective technical, coverage, reimbursement, and health economic information regarding its medical technologies. Companies also may collaborate with Health Care Professionals, patients and organizations representing their interests, to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patient access to medical technology. These items and services have no independent economic value and should be exempt from reporting. Section X of AdvaMed’s Code of Ethics establishes guidance on the ethical provision of such information.
J. Reporting of stock options

Stock options present complexities in reporting, and to establish a uniform and administrable approach, AdvaMed recommends that CMS provide guidance such that companies report in the year granted.

3. Exclusions

A. Definition of “product samples”

CMS should clarify in regulatory guidance that for purposes of the Sunshine statute, there are two general types of product samples in the medical device industry exempt from reporting:

- **Single Use Disposable Devices.** Companies provide physicians and/or patients with samples of single-use disposable devices, such as advanced wound care bandages and catheters. Since a patient’s condition might not respond to a particular device, drug, or other treatment, a physician may want to provide a patient with samples to evaluate the patient’s response. In addition, these products may be used in connection with a larger treatment protocol using other manufacturers’ devices, and it therefore is necessary to evaluate compatibility. In other cases, device samples or starter kits are furnished directly to patients, for example a short term supply of testing strips may be provided to a patient who has just learned of a diabetes diagnosis.

  Single use disposable samples serve a genuine educational or evaluative function, and have no economic value.

- **Demonstration Devices.** Generally, in discussing treatment options or when preparing a patient for surgery, a physician will describe the procedure, the surgical approach, the use and function of implantable devices and other treatment factors. If the patient is to receive an implantable device, such as a spinal implant, artificial knee or hip, it is crucial to demonstrate how the implant will fit within the human structure, how the implant will function, and describe the overall implantation procedure.

  Demonstration devices serve a genuine educational function and have little independent economic value. These are typically labeled SAMPLE and “Not for Implant” and are clearly not intended for actual clinical use, but rather to educate the patient and facilitate optimal medical decision-making.

In all cases, samples are provided to educate patients, ensure use of the most appropriate technology and otherwise enhance patient care and safety and do not provide any direct benefit to the provider. Device samples do not have an economic value and should be
exempt from reporting. In fact, the administrative costs associated with tracking and reporting device samples would discourage the use of beneficial device samples. (In fact, some companies have opted to no longer provide demonstration devices to Vermont-licensed HCPs due to the administrative costs and impracticalities of tracking in connection with that state’s transparency law.)

Further, to ensure that medical device sampling is in the best interests of patient care, 2009 amendments to the AdvaMed Code provides substantive guidance to medical device companies to ensure the propriety of sampling practices. For example, the Code states that companies should provide health care professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products, and furnish samples only to the extent necessary to allow a reasonable evaluation.

B. Definition of “educational materials that directly benefit patients or are intended for Patient use”

AdvaMed recommends that explanatory patient brochures among other educational materials should not be reportable. Under Section IX of AdvaMed’s Code of Ethics, a company occasionally may provide items to health care professionals that benefit patients or serve a genuine educational function for health care professionals. This would include, for example, patient educational brochures or posters, used for educational purposes, among others. These items do not have independent market value and should be excluded from reporting.

C. Services provided by an on-site physician who staffs a clinic for employees at the manufacturer’s site.

This type of activity is sometimes offered to employees to maintain their health and welfare. Providing this type of primary care is often what the physician does for his/her living. This is distinct from physicians who practice in private clinics or hospitals and also serve on industry advisory boards. Therefore, it should not be reportable.

D. Payments to physicians who provide review and evaluation of disability claims for human resources (“HR”) departments.

As noted above, this type of activity is part of the administration of a company’s day-to-day employment management activities and should not be made public. This type of service is distinct from serving on an industry advisory board and should not be reportable.
E. Products or services provided as part of a product recall

While recalls of medical technologies are uncommon, there are a variety of services companies must provide if a recall does occur, including additional training for physicians, which should not be considered a “transfer of value.” In some cases, that training may involve travel to a centralized training facility, which would normally trigger a reporting obligation under the Sunshine statute. However, in the case of a recall, companies may provide such training to physicians. In those cases, physicians may be uncomfortable about being identified in a public database that otherwise lists voluntary activities involving physicians and industry and public disclosure might discourage physician participation. Given that activities pursuant to a recall are a matter of FDA compliance and patient safety, payments related to such activities should be exempt from reporting.

F. Recruiting Costs

Company costs and recruitment fees incurred in connection with the recruitment, interviewing and review of covered recipient candidates for employment, should not be treated as transfers of value, and therefore should not be subject to reporting.

4. Delayed Publication for Payments Related to Clinical Investigations and Product Development Agreements

A product development agreement should be defined as one in which an applicable manufacturer or distributor engages a covered recipient for the purpose of making an explicitly defined contribution to (1) the research and/or development of a new product or technology or (2) an improvement to or new application of an existing product or technology.

To ensure uniformity and certainty, CMS should develop guidance that the reporting obligation is triggered by the payment date. Because companies are in the best position to know when products are approved/cleared by FDA, companies should have the obligation to report to CMS, by the next reporting deadline, once the company receives notice of FDA approval/clearance for the relevant product developed or the agreement. Whether publication is triggered by a company report of FDA approval/clearance, or CMS determines that the 4-year delayed publication period has been reached, CMS should have the responsibility for notifying companies, no less than 45 days in advance, when payment information subject to delayed publication will be publicly released.

Manufacturers should be required to track the product approval date for all clinical study related transactions.
Once the delayed publication period has expired and before the payment information is posted to the public database, CMS should allow a reasonable pre-posting period for covered recipients to review and verify, and for manufacturers to confirm, the payment information. Finally, when CMS posts payments for which delayed publication was in effect, CMS should identify those payments on the website in a clear manner so that the information and context surrounding those payments are understandable to patients. Consistent with the statutory language, payments subject to the delayed posting should be exempt from FOIA until they are posted.

In developing guidance to implement this section, CMS should allow flexibility to account for the wide variety of arrangements structured to develop new medical technologies. For example, for certain product development agreements, payments may be structured on a milestone basis, with multiple payments made over the course of a single agreement. In the case of product development agreements of a long duration, expiration of the delayed disclosure period for a single payment should not trigger disclosure of all subsequent related payments.

Last, CMS should publish the procedures and controls it will use to ensure data furnished by manufacturers will be separated from other data, and reserved for delayed reporting. These procedures should ensure that there is a clear option for manufacturers to choose indicating that a particular payment should be subject to delayed disclosure.

5. Background Information on Industry-Physician Relationships

The public database should include a dedicated statement that describes the value of interactions between covered recipients and manufacturers of medical technologies. The statement should discuss the various forms of interactions that occur and should identify the benefits of these interactions to patients and to continued innovation in medical care. CMS should seek stakeholder input before proposing this statement and provide an opportunity for public comment before finalizing the language in the statement.

In addition, CMS should provide companies an option to provide additional explanation and content surrounding each transfer of value that is reported. While the Sunshine Provisions require companies to provide a description of the nature of the payment (e.g. consulting fees, honoraria, travel, etc.), companies should have the opportunity to provide additional context about the specific nature of the payment.
6. Definition of “Manufacturer”

Companies should not be required to report transfers of value from distributors who take title of the product and who are not affiliated with or under common ownership with the manufacturer. By contrast, manufacturers who use independently contracted sales reps and/or distributors who do not take title to the product should be required to report transfers of values made by those entities because they are acting as an agent of manufacturers. Similarly, activities of a manufacturer’s contractors and agents who are involved in the sales, marketing or promotion of the manufacturer’s products should be reportable when such contractor or agent is acting at the direction of the manufacturer and the manufacturer has knowledge of the identity of the physicians receiving the transfer of value.

7. Recommendation on Acquisitions

Acquisitions present unique technical challenges for companies as they work to comply with the Sunshine provisions. Acquisitions most likely will not coincide with the close of a Sunshine reporting period, and the parties to the acquisition may use different tracking programs, which must be integrated post-transaction to enable single reporting by the consolidated entity. In addition, it is possible that the acquiring company will need to address problems in the tracking system of the acquired company. It will take time and resources for the acquiring company to merge multiple tracking programs into a seamless system. Therefore, CMS should provide a grace period in the case of an acquisition, merger and similar corporate transactions so that companies have sufficient time to harmonize tracking systems following the acquisition. Additionally, companies should not be held liable for the past reporting failures of a newly acquired company. An acquiring company would be obligated to report payments made by the acquired company only after the date that the acquisition becomes complete.

8. Preemption of State Laws

Federal preemption of duplicative state laws is a critical component of the Sunshine provisions. It is essential that patients have a single, comprehensive source of information about industry relationships with covered recipients; not only will such a system provide a clearer understanding to patients about the nature of these arrangements, it will also make public reporting more efficient for companies.

CMS should clarify the scope of preemption afforded by the statutory text; in other words, CMS should annually clarify exactly which state laws (or parts of state laws) it considers to be preempted by the federal law. This will ensure a clear and predictable environment for covered recipients, companies and state legislatures. AdvaMed recommends that CMS should establish a process to proactively monitor state laws and assert preemption where appropriate. CMS should also provide a process for companies who become aware of a duplicative state law to bring that state law to the attention of CMS.
9. Implementation/Operational Issues

CMS should give reporting entities an opportunity, no less than 45 days before payments are publicly posted, to preview the payment information that will be posted. Such preview should be secure so that manufacturers cannot view other manufacturer’s data. That preview date should be the date that triggers the 45-day correction period. Similarly, covered recipients also should be provided a process to check information that has been reported by industry for them before it is publicly posted, and CMS should publicize this opportunity so that covered recipients receive notification and reminders to check their information. The preview data should be in a downloadable format with the ability of companies and covered recipients to extract their individual data so they may verify it.

This preview period is essential to achieve the statutory intent of protecting confidential, proprietary company information on research and development. Providing an opportunity to preview the information will also protect covered recipients from the release of inaccurate information that would be viewed by the public. In addition, given the tremendous volume of information that CMS will be receiving and managing, CMS should include in its regulations a section detailing what systems companies will be required to utilize in submitting data, and extensive testing is needed before the public website goes live.

After the 45-day correction period expires, it is possible that there will be circumstances in which companies discover good faith errors or mis-identified transfers of value. In these cases, CMS should provide companies with a process for resolving such errors in a reasonable period of time.

Also, there may be instances in which a covered recipient disputes the transfer of value amount or other content reported by a manufacturer. If the covered recipient raises an issue during the 45-day correction period, or after that correction period has expired, CMS should refer the covered recipient to the manufacturer to resolve the issue.

CMS should publish guidance describing exercise of agency discretion in the application of its sanction authority. The guidance should clarify that penalties will not automatically apply for good faith errors, misclassifications, or under- or over-reporting, even if those errors are uncovered after the 45-day correction period. That is, guidance should distinguish administrative actions applicable to innocent mistakes after reasonable diligent efforts vs. intentional abuse/disregard. In addition, the correction period should begin on the date the error is discovered by the company or covered recipient, not the date the error was made.
The Secretary is required to consult with HHS OIG, industry, consumers, consumer advocates, and other interested parties. We were pleased to learn during CMS’s Special Open Door Forum that it plans to proceed with implementation of the Sunshine provisions through a formal notice and comment rulemaking. We agree that in order to ensure broad stakeholder input, CMS should propose implementing guidance, standards, definitions and procedures under a formal notice and comment rulemaking with at least 60 days for public comment before finalizing the regulation.

In addition, following the initial reporting period, CMS should provide another opportunity for stakeholders to provide input and comment to CMS to enable CMS to provide additional clarification or procedures where needed to ensure consistent application among all reporting entities and accurate understanding of the information by consumers.

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AdvaMed appreciates the enormous technical and other complexities associated with implementation of the Sunshine provisions. We thank you for considering these comments and recommendations, and AdvaMed looks forward to actively engaging in continued dialog with the Administration and CMS as the guidance process proceeds.

Sincerely,

Stephen J. Ubl
President

cc: Anthony Rodgers, Deputy Administrator and Director
    Peter Budetti, Deputy Administrator and Director
    Christopher L. White, Esq., AdvaMed
    Leah Kegler, AdvaMed