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"KEEP ON THE SUNNY SIDE"

SUNSHINE ACT COMPLIANCE FOR MEDICAL DEVICE COMPANIES

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"Keep on the Sunny Side": Sunshine Act Compliance for Medical Device Companies

In 1964, Johnny Cash recorded a version of the popular folk song, "***Keep on the Sunny Side***," with June Carter Cash for his album *The Junkie and the Juicehead Minus Me*. Although originally written in 1899, Cash's version of the song re-popularized it sixty-five years later due to Cash's unique, folksy and powerful voice:

There's a dark and a troubled side of life
There's a bright and a sunny side too
Tho' we meet with the darkness and strife
The sunny side we also may view

Keep on the sunny side, always on the sunny side
Keep on the sunny side of life
It will help us ev'ry day, it will brighten all the way
If we'll keep on the sunny side of life

The storm and it's fury broke today
Crushing hopes that we cherish so dear
The clouds and storms will, in time, pass away
The sun again will shine bright and clear.

Keep on the sunny side, always on the sunny side
Keep on the sunny side of life
It will help us ev'ry day, it will brighten all the way
If we'll keep on the sunny side of life

More recently, the song caught my attention while preparing a compliance training presentation for a client's national sales meeting. While I enjoy any catchy, toe-tapping country song, as well as most songs from the Man in Black, I found the lyrics to "Keep on the Sunny Side" particularly relevant to the Physician Payments Sunshine Act, 42 U.S.C. § 1320a-7h, and its

reporting obligations. Indeed, it could be said that the song's lyrics reiterate three best practices for Sunshine Act compliance:

I. Medical Device Companies Must Develop Policies and Procedures to "Keep on the Sunny Side" of Sunshine Act Compliance.

The lyrics of Cash's song highlight the importance of choosing between "a dark and troubled side of life," and "a bright and sunny side too." A similar choice exists for medical device companies and their employees relating to Sunshine Act compliance. In our vast healthcare compliance experience, which includes counseling clients on regulatory policies and procedures, conducting investigations regarding alleged misconduct, and completing assessments to evaluate a client's adherence with regulatory obligations, ***we have frequently observed that the fundamental difference between compliant and noncompliant conduct generally amounts to nothing more than an intentional and conscious choice of an individual***. Thus, the dichotomy between the "dark and troubled side of life," and the "bright and sunny side" in Cash's song provides a useful reminder about the importance of individual decision-making for regulatory compliance. To encourage appropriate decision-making it is critical for medical device companies to establish, implement and enforce policies and procedures for Sunshine Act compliance.

Implementing an appropriate Sunshine Act policy requires a fundamental understanding of the Act and its obligations. The Sunshine Act, also known as Section 6002 of the Patient Protection and Affordable Health Care Act, is a federal law intended to promote financial transparency in healthcare by requiring the publication of information about financial relationships between the pharmaceutical and medical device industry, and healthcare providers. Notably, the Act does not bar "remuneration" otherwise covered under the federal Anti-Kickback Statute; it merely requires companies to report payments as well as investment interests

Generally, the Act requires manufacturers of covered drugs, devices, biologicals, or medical supplies (referred to as "**applicable manufacturers**"), as well as applicable group purchasing organizations ("**GPOs**"), to annually submit information for the preceding calendar year about payments or other transfers of value ("**TOVs**") to a "covered recipient," which generally includes teaching hospitals, physicians, nurses, physician assistants and other healthcare professionals. A TOV is defined under the Act as any payment or other transfer by an applicable manufacturer to a covered recipient that does not fall within one of the excluded categories under the Sunshine Act. A TOV includes but is not limited to research-related payments, honoraria, gifts, travel expenses, meals, grants, and other compensation.

The information to be reported under the Act includes, but is not limited to, the date and amount of the payment or TOV, information about the covered recipient, and details about the medical products associated with the transaction. This data must be filed on or before March 31st of each calendar through the Open Payments System established by the Centers for Medicare and Medicaid Services ("**CMS**"). The Act states:

> On March 31, 2013, and on the 90th date of each calendar year beginning thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information with respect to the preceding calendar year: (i) ***the name*** of the covered recipient; (ii) ***the business address*** of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient; (iii) ***the amount of the payment or other transfer of value***; (iv) ***the dates*** on which the payment or other transfer of value was provided to the covered recipient; (v) ***a description of the form of the payment*** or other

transfer of value; (vi) ***a description of the nature of the payment*** or other transfer of value; (vii) if the payment or other transfer of value is ***related to marketing, education, or research*** specific to a covered drug, device, biological, or medical supply, the name of that covered drug, device, biological, or medical supply; and (viii) ***any other categories of information*** regarding the payment or other transfer of value the Secretary determines appropriate.

42 U.S. Code § 1320a–7h.

Finally, a manufacturer's reporting obligation requires information to be reported in a timely, accurate, and complete manner. Failure to report information in this manner may result in the imposition of financial penalties under the Act and its corresponding regulations. *See* 42 CFR 402.105(d)(5) ("CMS or OIG may impose a penalty of not more than $10,000 as adjusted annually under 45 CFR Part 102 for each failure of an applicable manufacturer or an applicable group purchasing organization to report timely, accurately, or completely a payment or other transfer of value or an ownership or investment.") The federal agencies responsible for enforcing Sunshine Act reporting violations are CMS, the Department of Justice ("DOJ"), and the Department of Health and Human Services, Officer of Inspector General ("HHS-OIG"). To better understand Sunshine Act reporting requirements and the relevant best practices, the following section briefly summarizes the specific components of the Act:

A. Applicable Manufacturer

An "applicable manufacturer" is any "manufacturer 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. 42 USC § 1320a-7h(e)(2). An entity is a "manufacturer of a covered drug, device, biological, or medical supply" if the entity is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply. *See* 42 U.S.C. § 1320a-

7h(e)(9) (this also includes any entity under common ownership with another entity that provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply). While this broad definition covers most medical device companies, certain companies may be eligible for more limited reporting requirements under 42 C.F.R. § 403.904, which exceptions are not detailed in this Client Alert.

Finally, a covered drug, device, biological, or medical supply product generally includes any product for which payment is available under the United States Medicare, Medicaid, or the Children's Health Insurance Program. For drugs and biologics, the definition is limited to those that, by law, require a prescription to be dispensed. For medical devices (or medical supplies that are medical devices), the definition is limited to those that require US Food and Drug Administration (FDA) pre-market approval or notification. A "covered product" is specifically defined as "any drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (or a waiver of such plan), either separately (such as through a fee schedule or formulary) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system) and which is of the type that in the case of a . . . (2) Device (including a medical supply that is a device), by law, requires premarket approval by or premarket notification to the FDA.

B. Payments, TOVs, and Ownership and Investment Interests

Under the Act, applicable manufacturers must report direct and indirect "payments and other transfers of value" they provide to covered recipients or to entities or individuals at the request of, or designated on behalf of, covered recipients. 42 C.F.R. § 403.904. Direct payments are self-

explanatory and involve any transfer of money to a covered recipient. Indirect payments are those payments made to a covered recipient through a third party, where the applicable manufacturer "requires, instructs, directs, or otherwise causes" the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient.

There are exceptions to TOVs and/or payments reportable under the Act. For example, an indirect payment may be excluded from reporting if it was provided to a covered recipient and the applicable manufacturer "does not know...the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year". Other TOVs excluded from reporting obligations include:

- Educational materials that directly benefit patients;
- Product samples (including coupons and vouchers) not intended to be sold and intended for patient use;
- Indirect payments or other transfers of value where the applicable manufacturer does not "know" the identity of the covered recipient;
- In-kind items used in the provision of charity care;
  Discounts and rebates; and
- Payments or other transfers of value made solely in the context of personal, non-business related relationships.

There is also an exclusion for TOVs under specified monetary limits on a single and annual aggregate basis to a single covered recipient. The total value of all such excepted TOVs is updated annually. For the calendar year 2023, these amounts are $12.69 per individual transfer and $126.89 in the aggregate.

Finally, the Sunshine Act requires each applicable manufacturer to report information regarding any "ownership or investment interest" (other than an interest in a publicly traded security or mutual fund) held by a physician (or his immediate family member) in the reporting manufacturer. This is

referred to as "OII" reporting and can become quite complicated based on the specific circumstances of the ownership and investment interests. Accordingly, the specific requirements for OII reporting are not detailed in this Client Alert.

C. Covered Recipients

As stated above, the reporting obligation under the Act is based on any TOVs or payments to a covered recipient. **A covered recipient generally includes physicians, nurses and other healthcare providers who are not bona fide employees of the applicable manufacturer.** In January 2021, the definition of covered recipient was expanded to include several new provider types, including physician assistants, nurse practitioners, clinical nurse specialists, etc. These provider types are broadly defined and should be considered as such when evaluating a reportable obligation. For example, a nurse practitioner is defined as any individual legally authorized to perform services in accord with an applicable state law and who meets the training, education and experience requirements as required by the State. Similarly, a clinical nurse specialist is any individual who is a registered nurse and is licensed to practice nursing in the State in which the services are performed and holds a master's degree in a clinical area of nursing from an accredited institution. In both instances, any TOV provided to a nurse practitioner or clinical nurse specialist is reportable.

D. Other Sunshine Act Obligations

In addition to the annual reporting requirement, the Sunshine Act also obligates reporting entities to maintain records related to reportable TOVs ***for at least five years***. This includes records of payments, transfers of value, and ownership and investment interests:

> Applicable manufacturers . . . must maintain all books, contracts, records documents and other evidence sufficient to enable the audit,

> evaluation, and inspection of the applicable manufacturer's . . . compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart.
>
> The items described in paragraph (e)(1)(i) of this section must be maintained for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site.

42 CFR § 403.912(c).

E. Federal Preemption and State Laws

Notably, the reporting obligations under the Sunshine Act provide a limited preemption of any state laws that require similar types of reporting information by a medical device company:

> In the case of a payment or transfer of value provided by an applicable manufacturer that is received by covered recipient . . . on or after January 1, 2021, subject to subparagraph (B), ***the provisions of this section shall preempt any statute or regulation of a State or of a political subdivision of a State*** that requires an applicable manufacturer . . . to disclose or report, in any format, the type of information . . . regarding such payment or other transfer of value.

42 US § 1320a-7h(b)(d)(3).

That preemptive effect does not apply, however, to differential reporting obligations by the states:

> Subparagraph (A) shall not preempt any statute or regulation of a State or of a political subdivision of a State that requires the disclosure or reporting of information – (i) not of the type required to be

> disclosed or reported under this section; (ii) described in subsection (e)(10)(B), except in the case of information described in clause (i) of such subsection; (iii) by any person or entity other than an applicable manufacturer or a covered recipient; or (iv) to a Federal, State, or local government agency for public health surveillance, investigation or other public health purposes or health oversight purposes.

42 US § 1320a-7h(b)(d)(3).

The limited preemption of the Sunshine Act means that states are permitted to impose different reporting obligations provided that such obligations to no exceed the scope of the limited federal preemption. For example, Massachusetts, Vermont and other states have reporting obligations similar to the Sunshine Act that medical device companies should be aware of, train on and prepare for in the event the Company conducts any business in such states. Similarly, California recently Assembly Bill 1278 (AB1278), which requires healthcare providers to provide patients with an electronic or written notice of the Open Payment program and its reporting obligations effective January 1, 2023.

F. Recent Changes to the Sunshine Act

Finally, in the calendar year 2022, CMS enacted a final rule implementing changes to data collection under the Open Payments program. *See* 86 FR 64996. These changes were enacted by CMS to clarify existing Open Payments requirements, as well as add provisions that stakeholders requested to improve the quality of the data and support the usability and integrity of the published data.

The changes to the Open Payments program are effective for data collection beginning in 2023 and will be applicable to data reported in the Open Payments program in 2024. A summary of the changes implemented to the Open Payments Program follows:

- Addition of a mandatory payment context field for records attributed to teaching hospitals
- Addition of the option for reporting entities to recertify annually even when no records are being reported by the reporting entity
- Disallowing record deletions without a substantiated reason
- Added definition for physician–owned distributorship(s) (PODs) as a subset of applicable manufacturers and group purchasing organizations as well as an updated definition of ownership interest
- Requirement for reporting entities to update their contact information
- Disallowing publication delays for general payment records
- Clarifying the exception for short-term loans; adding clarification that the exception for short-term loan applies for 90 total days in a calendar year, regardless of whether the 90 days were consecutive
- Removal of the option to submit and attest to general payment records with an "Ownership" Nature of Payment category.

II. Medical Device Companies Must Establish an Appropriate Tone from the Top to "Keep on the Sunny Side" of Sunshine Act Compliance

In addition to highlighting the importance of individual choices relating to Sunshine Act compliance, Cash's song also serves to provide another, important Sunshine Act compliance lesson. In the song, Cash instructs the listener to "***Keep on the sunny side***," because doing so will "***brighten all the way***." Through these lyrics, Cash instructs the listener to focus on the sunny side of life.

In many instances, the command to "keep on the sunny side" is reflective of the importance of executive leadership for healthcare compliance. After all, as with most corporate efforts, it is incumbent upon a company's

executive leaders to instruct and lead employees regarding appropriate conduct. Indeed, through appropriate leadership, a company can establish a tone from the top, which provides the values necessary to encourage compliant conduct and is the foundation upon which a company's culture is built. Therefore, by heeding Cash's advice and instructing employees to "keep on the sunny side," medical device companies can better establish a tone from the top. To this end, we have identified some (but not all) best practices that executive leaders should institute to promote Sunshine Act compliance:[1]

- ***Monitor and calendar relevant dates.*** The Sunshine Act includes several deadlines of note. For example, March 31st each year is the deadline for applicable manufacturers to submit Open Payments reporting data. May 15th of each year is the deadline for covered recipients to access their own data for review and correction. June 30th is the annual deadline for CMS to publish Open Payments reporting data received for the prior calendar year.

- ***Track and implement the annual de minimis thresholds set by CMS.*** CMS will annually update the de minimis thresholds for the "Small Payment Value Amount" and "Total Annual Amount," which are in effect from January 1st and run through December 31st. The 2023 thresholds are $12.69 and $126.89 respectively.

- ***Establish appropriate Sunshine Act tracking practices.*** To comply with its obligations, a company should implement appropriate Sunshine Act tracking practices that identify and ensure documentation of all events that are reportable under the Sunshine Act, including all payments or TOVs to covered recipients. Such tracking should also include a review of all agreements with health care providers (e.g., consulting contracts, clinical trial agreements, etc.) and any third

[1] This list is not exhaustive and can be implemented in addition to other Sunshine Act policies and procedures.

parties who may interact with health care providers on behalf of the company; maintenance of the company's internal assumptions document for each reporting year; and ensure adequate company resources to compile data compilation ahead of submission, resolve discrepancies/disputes with covered recipients, and submit corrected information *immediately* upon confirmation of an error or omission.

- *Implement appropriate meals, travel and expense reporting for healthcare providers.* By implementing appropriate expense thresholds and reporting practices for healthcare providers, the Company can simultaneously satisfy its obligations under the federal Anti-Kickback Statute as well as the Sunshine Act. Under these practices, all meals and expenses should be modest, occasional and reasonable, subordinate to the educational or informational purpose of a meeting with a healthcare provider, and consistent with CMS Open Payment reporting requirements and guidance. For example, when reporting the per-person cost of a group setting or buffet meal, CMS requires the reporting of the food and beverage amount (total value) as divided by the number of those that actually partake in the meal offered. If the de minimis threshold is crossed by this resulting amount, whether on a per-person or total basis, then the meal must be reported. Additionally, such policies should comply with any additional policies of the company, any trade associations, such as AdvaMed or MDMA, for whom the company is a signatory, and any updates to the Open Payments system or guidance issued by CMS.

- *Train employees regarding the CMS Open Payments System and User Guide.* One easy way for a company to comply with its Sunshine Act reporting obligations is to appropriately train its employees regarding the Open Payments system and reporting methodology to ensure the reportable information is properly filed in the first place. For example, CMS requires that organizations register through the **CMS Identity Management System** (IDM). This system will deactivate a user account if it is not logged into for 180 days. Through the IDM portal, the **Open**

Payments system can be accessed. The Open Payments system offers multiple "Roles," (Officer, Submitter, Attester, and Compliance) of varying functional access, for identifying the user accounts of reporting organizations. For additional details please visit the "Registration for Reporting Entities" page at www.cms.gov as well as the Open Payments User Guide.

III. Medical Device Companies Must Educate Employees About the Consequences of Misconduct to "Keep on the Sunny Side" of Sunshine Act Compliance

Finally, as Cash sings, a failure to focus on the "sunny side" can lead to a "dark and a troubled side of life." The same dynamic applies to Sunshine Act compliance. While noncompliance with the Act may inadvertently result, ***a company that is intentional in its compliance approach can mitigate adverse consequences of noncompliance and avoid the "dark and troubled side" of the Act.***

A. Sunshine Act Penalties and Enforcement

Nonetheless, the "dark and troubled side" from Cash's song alludes to the financial penalties (Civil Monetary Penalties or CMP) or the other enforcement activities that may be brought against a company for Sunshine Act violations. The type of financial penalties or other enforcement activity is based upon whether a company has unknowingly or knowingly failed to comply with Sunshine Act obligations.

For example, if an entity merely fails to report (i.e., was not a knowing failure to report) then that entity may be subject to a CMP of not less than $1,000 but not more than $10,000 as adjusted annually for each payment or transfer of value or ownership/investment interest that was not properly reported. *See* 42 US § 1320a-7h(b)(1); 42 CFR § 403.912(a). ***The total amount of CMPs***

that may be imposed with respect to a general failure to report shall not exceed $150,000 as adjusted annually. *Id.*

If, however, an entity knows that it has an obligation to submit the required, annual reporting and knowingly fails to do so, then the CMPs may be increased. In such instance, if an entity knowingly fails to report, then the CMPs that may be imposed shall not be less than $10,000 but shall not be more than $100,000 as adjusted annually for each payment or transfer of value or ownership/interest that was not knowingly reported. See 42 US § 1320a-7h(b)(2); 42 CFR § 403.912(b). The total amount of CMPs that may be imposed with a knowing failure to report shall not exceed $1,000,000 as adjusted annually. Id.

Finally, the total amount of CMPs that may be imposed on each applicable manufacturer is (1) aggregated separately; and (2) subject to a maximum combined total of $1,150,000 as adjusted annually. *See* 42 CFR § 403.912(c).

To determine the type of penalty to impose, CMS defines "knowingly fails" as having "actual knowledge of the information," acting "in deliberate ignorance of the truth or falsity of the information", or acting "in reckless disregard of the truth or falsity of the information". *Thus, if an entity has "actual knowledge" of its reporting obligation under the Sunshine Act, acts in deliberate ignorance of its obligations, or acts in reckless disregard of its obligations, then CMS and federal prosecutors would likely conclude the Company engaged in a "knowing failure to report," which can trigger the elevated CMPs referenced above*. It is likely that a company who did not know that it needed to be reporting, and failed to report at all, would qualify for the knowing failure standard. However, companies are expected to know the general laws governing TOVs and corresponding reporting obligations.

A Company's knowledge is not, however, the sole consideration when imposing penalties for violations of the Sunshine Act. *The regulations*

provide that several factors should be considered in evaluating the imposition of CMPs:

> In determining the amount of the civil monetary penalty, factors to be considered include, but are not limited to, the following:
>
> 1. The ***length of time*** the applicable manufacturer or applicable group purchasing organization failed to report, including the length of time the applicable manufacturer or applicable group purchasing organization knew of the payment or other transfer of value, or ownership or investment interest;
> 2. ***Amount of the payment*** the applicable manufacturer or applicable group purchasing organization failed to report;
> 3. **Level of culpability;**
> 4. **Nature and amount of information reported in error;** and
> 5. **Degree of diligence exercised in correcting information** reported in error.

See 42 CFR § 403.912(d).

Additionally, those additional factors set forth in 42 CFR § 402.11 are to be considered for the imposition of any penalties and assessments, this includes the basic factors stated in Section 402.111(a) (e.g., the degree of culpability, history of prior offenses, available resources, and other factors as justice may require) and the specific criteria in Section 402.111(b) (e.g., aggravating circumstances and mitigating circumstances).

B. Recent Sunshine Act Enforcement

Finally, as an example of the "dark and a troubled side of life" that can result from Sunshine Act violations, this Client Alert highlights two, recent Sunshine Act enforcement actions. Both actions illustrate an increasing use of the Sunshine Act as an enforcement tool for the federal government.

The first enforcement example concerns of underreporting of Sunshine Act data. On October 29, 2020, the DOJ announced the settlement of alleged violations with Medtronic USA, Inc. *See* https://www.justice.gov/opa/pr/medtronic. In that action, Medtronic agreed to pay $8.1 million to resolve allegations that it violated the False Claims Act by paying kickbacks to induce a South Dakota neurosurgeon to use certain Medtronic products, and an additional $1.11 million to resolve allegations that it violated the Open Payments Program by failing to accurately report payments it made to the neurosurgeon to CMS.

Specifically, the settlement concerned allegations that Medtronic agreed to the requests of South Dakota neurosurgeon, Wilson Asfora, M.D., to pay for events at Carnaval Brazilian Grill, a restaurant owned by Asfora in Sioux Falls, South Dakota. Medtronic allegedly paid for these events to induce Asfora to utilize Medtronic's SynchroMed II intrathecal infusion pump. Over a nine-year period, Medtronic allegedly paid for more than one hundred events at Asfora's restaurant at a value of approximately $87,000, but allegedly underreported those payments through the CMS Open Payments system. It was the fact that Medtronic failed to accurately, timely and completely report the TOVs that lead to the $1.11 million settlement for Sunshine Act violations.

The second enforcement example illustrates the concern of not reporting Sunshine Act data. As stated above, accuracy in Sunshine Act reporting is critically important. This is because transparency is the purpose of the Act, and the information reported through the Open Payments system helps government regulators ensure that certain payments do not constitute illegal inducements or kickbacks. To that end, if a Company fails to report accurate information, then substantial enforcement activity may result.

On May 19, 2021, the DOJ announced that Medicrea International, a French device manufacturer and its American affiliate, agreed to pay $1 million to resolve allegations of Sunshine Act violations based on failing to accurately

report physician-entertainment expenses through the Open Payments System. In this matter, the DOJ alleged Medicrea provided items of value in the form of meals, alcoholic beverages, entertainment and travel expenses to US-based physicians at events surrounding the Scoliosis Research Society's conference in Lyon, France. The DOJ alleged these TOVs were provided to the physicians to induce the purchase or order of Medicrea's spinal devices and were not reported through the Open Payments system.

C. Mitigating Sunshine Act Violations

Even in the event of a Sunshine Act violation, there are several measures a company may consider implementing to mitigate enforcement consequences. Some of these measures may be considered mitigating factors by CMS, the DOJ or the OIG and reduce the imposition of any CMPs or the likelihood of an enforcement action. *See* 42 CFR § 403.912(d); 42 CFR § 402.111(a) and (b). These include, but are not limited to:

- ***Complete a comprehensive review and evaluation of all TOVs for the reporting year.*** By completing a review and evaluation of all TOVs, a company can ensure its accurate, timely and complete submission of additional or amended Sunshine Act information. This should include an analysis of all travel, expense and other documentation for the relevant period of time. It will also likely require the creation of Sunshine Act reporting records.

- ***Promptly submit or amend a prior submission with accurate and complete information.*** If a company has discovered that its prior report was not correct, the company should file an amended submission to address all of the Open Payments information, including the following information required under 42 CFR § 403.904(c): (i) name of covered recipient; (ii) address of the covered recipient; (iii) identifiers for non-teaching hospital covered recipients,

including the specialty, NPI, and state professional license numbers; (iv) the amount of payment or other transfer of value (it made to a group of covered recipients it must be distributed appropriately among the individual covered recipients); (v) the date of the payment or transfer of value; (vi) the form of payment or transfer of value); (vii) the nature of payment or transfer of value (i.e., whether a consulting fee, compensation, honoraria, gift, entertainment, food and beverage, etc.); (viii) the related covered device; (ix) eligibility for delayed publication (if applicable); (x) payments to third parties (if applicable); (xi) payments or transfers of value to physician owners or investors (if applicable); and (xii) additional information or context for the payment or transfer of value).

- *File an assumptions document to explain any amended or untimely reporting by a company.* The Company should consider whether an assumptions document should be filed through the Open Payments system under 42 CFR § 403.908(f) to explain the assumptions, methodologies, or other reasons for the amended reporting by a Company. Alternatively, another disclosure by a company to the Open Payments Compliance Team that identifies a prior reporting violation or mistake, as well as the efforts taken by the company to correct that mistake and/or violation and provide accurate, timely and complete information may be an appropriate affirmative disclosure to inform CMS of the company's efforts to diligently resolve the issue and mitigate any financial penalties or other enforcement actions.

- *Implement, or revise a Sunshine Act policy.* If a company fails to comply with its Sunshine Act obligations and does not have an existing policy, the company should promptly institute a Sunshine Act Policy that identifies the purpose of Sunshine Act compliance, the scope of the policy (which should apply to all Company employees, distributors, agents and independent contractors), and the responsibilities for compliance. These responsibilities should include reviewing and approving documentation, collecting and monitoring

of Sunshine Act reporting information from employees, and maintaining any internal assumptions documents for Sunshine Act reporting. It should also encompass the submission, review and audit of Sunshine Act reporting information annually, as well as implement enforcement measures for violation of the Company's policy. If a company fails to comply with its obligations and has a policy in place, then the Company should evaluate and revise its existing policy as necessary to ensure future compliance consistent with the guidelines above.

- **Conduct additional, effective Sunshine Act training.** If a company fails to comply with its Sunshine Act violations, the company should implement or revise its Sunshine Act compliance training. Compliance training should educate Company personnel about the Company's reporting obligations and procedures for tracking reportable payments and transfers of value, should be completed by all Company employees and any future new-hires within thirty (30) days of the commencement of employment, should be periodically updated to comply with any updates or revisions to the Sunshine Act or its reporting obligations, should incorporate the Company's state law obligations, if any, and should be completed at least annually to ensure employee compliance with the Company's policies and reporting requirements.

IV. CONCLUSION

As Cash sings, "There's a dark and a troubled side of life, There's a bright and a sunny side too, Tho' we meet with the darkness and strife, The sunny side we also may view." While this song was not written about Sunshine Act compliance, it serves as a helpful surrogate to remind medical device companies about the importance of Sunshine Act compliance. By implementing appropriate policies and procedures, establishing a clear and

instructive tone from the top, and implementing effective compliance training, medical device companies can more effectively position their organizations to "Keep on the Sunny Side."

DuVal & Associates

Drug, Device and Food Law

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