



## **The National Physician Payment Transparency Program (the “Sunshine Act” or the “Open Payments Program”)**

The National Physician Payment Transparency Program, also known as the “Sunshine Act” or the “Open Payments Program”, a provision of the Patient Protection and Affordable Care Act, was enacted by Congress in 2010 as part of the healthcare reform law. The Sunshine Act is intended to provide more transparency in the relationships between pharmaceutical and medical device manufacturers and healthcare providers, by requiring manufacturers to report payments and other “transfers of value” to physicians and U.S. teaching hospitals to the Centers for Medicare and Medicaid Services (CMS) on an ongoing basis. ZOLL Medical Corporation (“ZOLL”) is committed to complying with these new requirements, and believes that disclosing payments related to interactions with healthcare providers will foster the public trust and confirm our commitment to ethical behavior.

The Sunshine Act implementing regulations require ZOLL to track payments and other transfers of value that occurred on or after August 1, 2013. ZOLL will report data regarding these payments and transfers of value to the CMS on an annual basis. Examples of the types of payments and transfers of value to physicians and teaching hospitals that ZOLL is required to report include, but are not limited to: gifts, food and beverages, travel expenses, honoraria, research studies, including the value of supplies and equipment, grants, education, charitable contributions, direct compensation for serving as a faculty or speaker at medical education programs, consulting fees, ownership or investment interest, royalties, license fees and other speaking fees. CMS will publish the data submitted by ZOLL and other manufacturers on its Open Payments Program website (<http://go.cms.gov/openpayments>), which will be accessible by the public beginning in September 2014, and updated on an annual basis. Prior to the

posting of data, CMS will allow recipients to review and dispute data that a company discloses through a formal review and dispute period. Please visit the CMS Open Payments Program website for more information on this process.

The accompanying list of frequently asked questions provides additional information about ZOLL compliance with the Sunshine Act and the CMS Open Payments Program requirements, and how these requirements may affect you. If you have any questions about the CMS Open Payments Program or about the types of payments or transfers of value that ZOLL is required to report, please contact us.

## **Frequently Asked Questions**

### **1. What is the Sunshine Act?**

The National Physician Payment Transparency Program (Open Payments), also known as the Sunshine Act, is a section of the Patient Protection and Affordable Care Act of 2010 that requires pharmaceutical and medical device companies to report to the Federal government regarding certain payments and transfers of value they make to physicians and teaching hospitals. The Sunshine Act also requires these companies to report any physician ownership or investment interests in the company.

### **2. Which healthcare professionals qualify as a “physician” for reporting purposes?**

The term “physician” includes only the following types of healthcare professionals: Medical Doctors (MD), Doctors of Optometry (OD), Doctors of Osteopathy (DO), Doctors of Dental Surgery and Doctors of Dental Medicine (DDS, DMD), Doctors of Podiatry (DPM), Doctors of Chiropractic Medicine (DC). Payments and transfers of value need to be reported only for those physicians who are currently licensed to practice in the United States.

### **3. Which institutions qualify as a “teaching hospital” for reporting purposes?**

CMS maintains a list of teaching hospitals. Institutions are included on the CMS list if they received a payment in the prior calendar year under one of the defined Medicare Direct Graduate Medical Education or Independent Medical Education programs. ZOLL will use a matching process to identify payments and other transfers of value to institutions on the CMS teaching hospital list.

### **4. What types of payments must be reported under the Sunshine Act?**

Under the Sunshine Act, ZOLL must report payments and other transfers of value made to US physicians and teaching hospitals including the cost of meals provided to physicians in any setting, payments made as part of a contracted service such as speaker programs, advisory boards, consulting and other research and clinical trials, travel expenses, educational items, stocks, grants, and devices and other products donated to physicians for use in their practices.

### **5. What research-related payments and transfers of value will be reported?**

All research-related payments and transfers of value to physicians and teaching hospitals will be reported to CMS. This includes payments and transfers of value relating to all phases of research and development, and support for investigator-initiated investigations. Reporting will include both cash payments and the value of in-kind support, such as ancillary supplies and equipment provided by ZOLL for purposes of conducting a study or trial. Pursuant to the Open Payments implementing regulations, research-related payments will be reported separately from other payments and will include the name and address of the individual or entity paid, information regarding each physician principal investigator, and the total amount of the research payments.

### **6. What information about physicians will be reported to CMS?**

Each line item that ZOLL is required to report to CMS will be available on the public report in detail including but not limited to: Manufacturer’s Name, Physician or Hospital Name, Specialty of Physician, Business Address, Amount of Payment or Transfer of Value, Date of Payment, Form of Payment (e.g., cash, in-

kind items or services, stock), Nature of Payment (e.g., consulting, food, travel, education), Name(s) of the related covered device or product, as applicable

## **7. Are there any types of payment that don't need to be reported?**

Yes. The following payments and transfers of value are among the exceptions to the reporting requirements:

**Office staff meals:** In general, meals are reportable only for the physicians who actually partake in the meal. Meals provided to the office staff of the physician typically are not reportable. When ZOLL calculates the value of physician meals, we will divide the total cost of the meal by the total number of people who ate (including physicians and non-physicians) and will report only the proportional cost that is attributable to each physician. For example, if ZOLL spends \$200 on a meal for five physicians and five non-physician staff members, the physician meals will be reported at \$20 each and the staff meals will be excluded from ZOLL reporting.

**Meals at conferences and large-scale events:** The Open Payments Program implementing regulations do not require reporting of buffet meals, snacks, soft drinks, or coffee made generally available to all participants at major conferences or other large-scale events.

**Patient educational materials:** The Open Payments requirements also exclude from reporting educational materials and items that directly benefit patients or are intended to be used by or with patients from the reporting requirements. However, textbooks, journal reprints and other materials that are not for patient use do not fall within the exclusion.

**Speaker compensation at accredited continuing medical education:** Payments to physicians who serve as speakers at industry-supported independent continuing medical education (CME) generally are not required to be reported, if the event is certified or accredited by ACCME or certain other organizations, ZOLL does not pay the physician directly and ZOLL does not select or suggest the individuals to be used as speakers.

Samples and coupons: Drugs, medical devices, and medical supplies provided as samples are excluded from reporting if they are intended for patient use and not intended to be sold. Coupons or vouchers intended to defray the costs of these products are also excluded from reporting so long as they are intended for patient use. Short Term Loans: The loan of a device or product to a physician for a short-term trial period to permit evaluation of the device is excluded from reporting, so long as the duration of the loan does not exceed 90 days.

**9. Can a physician opt out of having information reported?**

No, the law requires that ZOLL and all other companies report qualifying payments and transfers of value. The only way to avoid appearing on ZOLL disclosures to CMS is to decline meals, educational materials, grants and all other reportable payments and transfers of value. At ZOLL-sponsored events and in-office interactions there will be a sign-in sheet for participants. You will have the option to opt out of receiving ZOLL's in-kind benefits (meals, parking validation, travel and hotel accommodations, etc.). If you opt out of receiving these benefits no payments will be reported for that event or interaction.

**10. If a payment is made to another recipient, such as a charity, on behalf of or at the request of a physician, is it reportable?**

Yes. If a payment is directed to a charity or other third party on behalf of or at the request of a physician, it is reportable as a transfer of value to the physician.

**11. If a payment is made to a physician's group practice, rather than directly to the physician, is it reportable?**

Yes. A payment made to a physician's group practice, rather than directly to the physician, is still reportable as a payment to the physician who requested the payment or on whose behalf the payment is made.

## **12. How do the Open Payments reporting requirements affect state-based disclosure requirements?**

The Open Payments reporting requirements preempt (or override) state laws and regulations that require pharmaceutical and device manufacturers to report information to state authorities about payments and other transfers of value to individual physicians and teaching hospitals. However, states are still permitted to require reporting of additional information that is different from the scope of the information reported to the federal government. Thus, different information relating to payments and transfers of value to physicians and teaching hospitals and information about payments to health care providers that are not physicians or teaching hospitals may still be reported at the individual state level, generally based on where the health care provider is licensed or practices.

## **13. When will the first payments be reported to CMS? When will CMS disclose the information it has received?**

The first report will cover payments or other transfers of value during the period of August 1, 2013 to December 31, 2013. CMS is expected to aggregate the information reported by ZOLL and other manufacturers and post that information on a dedicated website by September 30, 2014.

## **14. Will CMS provide a mechanism for reviewing and disputing payments and other transfers of value?**

CMS is required to provide physicians and teaching hospitals with access to a secure website so they can review the payments and transfers of value attributed to each of them, and to dispute payments or other transfers of value that may be inaccurate prior to the information being made public. CMS is projected to provide access to this secure website at least 60 days before the Sept. 30, 2014 publication date.

**15. I have questions about which payments or transfers of value ZOLL will report – who can help answer my questions?**

If you have any questions about the types of payments or transfers of value that ZOLL is required to report, please contact us. If you have general questions about the Sunshine Act or the Open Payments Program, the CMS Open Payments Program website is also a good resource, and can be accessed at National Physician Payment Transparency Program website:

(<http://go.cms.gov/openpayments>).