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Life Sciences Health Industry

If you have questions or would like additional information on the material covered in this Alert, please contact one of the authors:

**Elizabeth B. Carder-Thompson**
Partner, Washington, D.C.
+1 202 414 9213
ecarder@reedsmith.com

**Daniel Kadar**
Partner, Paris
+33 (0)1 76 70 40 00
dkadar@reedsmith.com

…or the Reed Smith lawyer with whom you regularly work.

# Overview of Primary Provisions of U.S. and French Sunshine Reporting Requirements

2013 was a year of unprecedented scrutiny of financial relationships between manufacturers and health care professionals, such as physicians. Both the United States and France imposed sweeping new reporting and disclosure requirements in an effort to provide transparency and, theoretically, to enable the public – including patients – to make informed treatment decisions and assess possible conflicts of interest. Both sets of requirements carry potentially large financial penalties for failure to report and for incorrect reporting. For manufacturers operating globally, compliance with these provisions will be an ongoing challenge.

At the same time, a review of the highlights of the two Sunshine Acts demonstrates that transparency is not necessarily the same on one side of the Atlantic as the other.

Under the new law, U.S. manufacturers will primarily be reporting payments and transfers of value to physicians and teaching hospitals, along with physician ownership information. In contrast, manufacturers operating in France have reporting obligations on a much broader list of HCPs than in the United States, and they must also identify the nature of the agreements they sign with such HCPs in order to know what data they need to disclose. Further, they must report to several authorities, comply with data protection regulations, and ensure compliance regarding cosmetics products.

Therefore, a summary chart may be helpful as a first step to identify the scope of the transparency requirements in both systems. The chart below compares and contrasts the primary requirements of the two sets of Sunshine reporting requirements. Please note that the law and regulations in both countries are highly complex, with detailed and sometimes confusing definitions and regulatory interpretations; this overview is designed primarily to offer an “at a glance” comparison. The authors would be happy to answer questions or provide additional information on specific aspects of either set of Sunshine provisions; and please click here for additional information about the Reed Smith Health Care practice.

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| TOPIC | U.S. SUNSHINE | FRENCH SUNSHINE |
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| **CITATIONS/ LINKS** | 42 USC § 1320A-7h; 78 Fed. Reg. 9458 (Feb. 8, 2013) | French law No 2011-2012 dated 29 December 2011; Decree No. 2013-414 dated 21 May 2013; Order of 03 December 2013 related to the unique transparency state portal |
| **EFFECTIVE DATES** | Per the regulations, manufacturers began collecting data 8/1/13; first report will be submitted 3/31/14 (reporting on period 8/1/13-12/31/13); CMS will release data on website 9/30/14.<br><br>However, CMA announced a two-phase registration and data-submission process for the 2013 Open Payments Program. Under Phase I (2/18/14 – 3/31/14), applicable manufacturers and applicable group purchasing organizations register and submit to CMS corporate profile information and aggregate 2013 payment data. Phase 2 begins in May, extends no fewer than 30 days, and includes submission of detailed 2013 payment data and legal attestation to the accuracy of the data. Both phases of data submission will be complete by August 1, when dispute-resolution process will begin. Per CMS, this phased approach is for the 2013 program year only. | Manufacturers began collecting data 1/1/12.<br><br>**Transitional provisions:**<br><br>First report was due to be submitted 6/1/13 (reporting period: 1/1/12-12/31/12); data also had to be released on the National Council Order and companies' websites 10/01/13. This timeline is subject to some flexibility because of inconsistencies in the implementation rules, and it also includes the first half of 2013, given the delays in implementing the system.<br><br>**Moving forward:**<br><br>• Disclosure of contracts:<br><br>At the latest, two weeks after the signature of the contract.<br><br>• Disclosure of benefits:<br><br>The information regarding benefits granted during the first civil semester will have to be transmitted before August 1, and published by the competent authority before October 1.<br><br>The information will have to be transmitted before February 1 for benefits granted during the second half of the preceding year and published before April 1. |
| **ANALYSES** | Overview and Analysis of the Proposed Federal Sunshine Regulations (Jan. 2012)<br><br>CMS Physician Payment "Sunshine" Final Rule – Overview and Analysis (Mar. 2013)<br><br>CMS Announces Data Collection for the Physician Payments Sunshine Act Will Not Be Required Before 2013 (May 2012) | 'Sunshine Act' à la française adopted on 29 December 2011. Healthcare and cosmetics companies will be subject to a tough transparency regulation in France (Jan. 2012)<br><br>A Brave New World? The "French Sunshine Act" imposes online disclosure of contracts with HCPs, as well as of payments of "advantages" to HCPs, dating back to 01 January 2012 (May 2013) |

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| **WHO MUST REPORT** | Manufacturers of "covered" drugs, devices, and supplies operating in the United States, i.e., products for which payment is available under Medicare, Medicaid and CHIP, and which require a prescription before dispensing (for drugs and biologicals) or premarket approval by or notification to FDA (for devices and supplies).<br><br>Distributors of covered products that take title must also report. Distributors not taking title will have to notify manufacturers for which they provide services of applicable payments and transfers of value. | Any company that manufactures or markets products regulated by the Medicine Agency ("ASNM"), including but not limited to, drugs, biological products, medical devices, devices for in vitro diagnosis, cosmetic products, tattooing products, biocide products, etc.<br><br>Any company that operates in France by providing associated service in connection with one of these products, such as:<br><br>• Technical services to use any product<br><br>• Communication and advertising to promote one of these products<br><br>Any company acting on behalf of a company that manufactures or markets such products. |
| **TO WHAT AGENCY MUST INFORMATION BE REPORTED** | Centers for Medicare & Medicaid Services of the U.S. Department of Health & Human Services | **Transition period:**<br><br>• Disclosure to the relevant HCP associations (seven HCP associations: physicians, dental surgeons, midwives, pharmacists, nurses, masseur-physiotherapists, podiatrists)<br><br>• Disclosure on company websites or dedicated websites for the filing<br><br>CAUTION: the format requested in particular by the French Medical association is NOT the same as the one set forth by regulation.<br><br>**Moving forward:**<br><br>A unique web portal has been set up by the French Government http://www.entreprises-transparence.sante.gouv.fr<br><br>First filings for the first half of 2013 are due by 28 February 2014 (extended deadline). |
| **PAYMENT THRESHOLDS** | Payments or transfers of value exceeding $10 (but payments of less than $10 must be tracked and reported if, in the aggregate, they exceed $100). | The Decree sets forth the threshold for disclosure at €10 (VAT included), but also makes a distinction between contractual remuneration and any other form of payment to HCPs that is NOT subject to disclosure (see below). |

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| **WHAT INFORMATION MUST BE REPORTED** | Payments and transfers of value from the applicable manufacturers to physicians and teaching hospitals, as well as physician ownership and investment interests in applicable manufacturers. | Companies must report any agreement entered into with HCPs, or benefits granted to HCPs, associations of HCPs, medical students, associations of medical students, associations of health system users, clinics and hospitals, foundations, medical societies and advisory societies, and companies operating in the health products sectors, including publishing companies, broadcasters of radio or television services, publishers of public online communications services, publishers of prescription and drug delivery assistance software, and legal entities providing training sessions for the covered HCPs.<br><br>(i) For any agreement entered into with HCPs, medical students, and associations, companies must disclose the following:<br>• The name and address, as well as (i) registration number, qualification and specialty (if applicable) for individual HCPs, (ii) educational establishment and professional number for medical students, (iii) names, and registered office for companies<br>• The date of the contract<br>• The purpose of the contract without violation of the confidentiality of commercial and industrial information<br>• No amount to be disclosed<br><br>(ii) For benefits provided to HCPs, medical students, and legal persons, companies must disclose the following:<br>• The name and address, as well as (i) registration number, qualification and specialty (if applicable) for individual HCPs, (ii) educational establishment and professional number for medical students, (iii) names, and registered office for companies of both the recipient of the benefits and the company<br>• The value of the benefits (including taxes) rounded to the nearest euro, date on which the benefits were granted, and the nature of each benefit (threshold: €10 incl. VAT)<br>• The period during which the benefits were provided (first or second half of the year) |
| **TYPES OF PAYMENTS THAT MUST BE REPORTED** | Generally, all direct and indirect payments or transfers of anything of value by applicable manufacturers, including indirect payments made to third parties at the request of or designated on behalf of physicians and teaching hospitals. | Every benefit in kind or in cash, direct or indirect. |

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| **CATEGORIES OF PAYMENTS TO BE REPORTED** | • Charitable contributions<br>• Food and beverage<br>• Speaker fee compensation<br>• Consulting fees<br>• Honoraria<br>• Gifts and entertainment<br>• Travel and lodging<br>• Education<br>• Royalties or licenses<br>• Current and prospective ownership or investment interests<br>• Grants<br>• Research<br>• Space rental/facility fees | • Charitable contributions<br>• Food and beverage<br>• Gifts and entertainment<br>• Travel and lodging |
| **CATEGORIES OF PAYMENTS THAT CAN BE EXCLUDED** | • Existing personal relationships<br>• Payments or transfers of value of less than $10 (unless annual value aggregates to $100)<br>• Educational materials that directly benefit patients or are intended for patient use<br>• Discounts and rebates<br>• In-kind items for the provision of charity care to patients<br>• Publicly traded fund payments<br>• Product samples<br>• Short-term (less than 90 days) loans of equipment or supply of disposable/single-use devices<br>• Contractual warranty<br>• Covered recipient acting as patient<br>• Provision of health care<br>• Nonmedical professional services<br>• Payments for physicians furnishing services as part of legal proceedings | • Benefits of value of less than €10 VAT incl.<br>• Payments made as contractual remuneration, such as speaker fees or consulting fees<br>• Payments made for commercial sales for goods and services<br>• Companies manufacturing or marketing cosmetic products, contact lenses, and tattoo products need only report clinical trial agreements or agreements related to safety evaluation and vigilance. Therefore, all other agreements can be excluded. |

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| **SPECIAL RULES FOR RESEARCH PAYMENTS** | Special reporting rules and forms apply for pre-clinical research and FDA Phases I-IV research, as well as investigator-initiated investigations. Manufacturers can request delayed publication on CMS' website for research payments, until (1) the covered product received FDA approval, licensure or clearance, or (2) four years after the date of the payment or other transfer of value, whichever occurs first, in order to protect confidentiality. | No special rules govern research. |
| **PROVISIONS ON OWNERSHIP/ INVESTMENT INTERESTS BY PHYSICIANS** | Applicable manufacturers and applicable group purchasing organizations (GPOs) must report certain information regarding ownership and investment interests held by physicians and their immediate family members, as well as payments and transfers of value to such physician owners and investors. | No special rules govern physician or GPO ownership or investment interests. |
| **HOW ARE DISPUTES HANDLED** | CMS will notify physicians and teaching hospitals of the payments and transfers of value reported by manufacturers, and the parties have 45 days to review the data. The parties then have 15 days to correct disputed data. | No special rules govern disputes. |
| **PENALTIES FOR NONREPORTING AND INACCURATE REPORTING** | Civil monetary penalties (CMPs) of $1,000 – $10,000 for each instance of non-reporting, up to a maximum of $150,000. Knowing failure to report is subject to CMPs of $10,000 - $100,000, up to a maximum of $1 million. CMPs for failure to report and knowing failure to report can be aggregated to a maximum of $1,150,000. | A fine up to €45,000 and additional sanctions. |
| **DATA PROTECTION CONCERNS** | | • Specific format set forth by the French Data Protection Authority CNIL for online disclosure<br>• HCP must be notified by the companies that they will disclose their related data on the French unique state portal for transparency purposes<br>• No prior notification obligation to the CNIL necessary unless disclosed data is transferred to the United States, or to any other country not offering adequate data protection according to EU regulation |