Here Comes the Sunshine Act: Impact on the Massachusetts Gift Ban and Reporting Law

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Among the myriad of provisions included in the final federal health reform law[1] is a first time broad national disclosure mandate on the interactions between industry and medicine. What was once known as the Physician Payment Sunshine Act [2] is now the law of the land.

Starting with calendar year 2012, and annually thereafter, payments or transfers of value worth over $10[3] made by pharmaceutical, medical device and biotechnology manufacturers operating in the U.S. or its territories[4] to physicians[5] or teaching hospitals must be tracked and will become reportable to the United States Department of Health and Human Services ("HHS"). The reported information,[6] which will identify the recipient, amount, and nature of each payment, will become part of an on-line searchable and downloadable public data base which is to "go live" on September 30, 2013.

The federal Sunshine data base is specifically designed to be "user friendly" to the "average consumer."

HHS is required to make the public data base searchable and in a format that is clear and understandable. It is to contain information that is presented by the name of the reporting company, the name, business address and specialty of the covered recipient, the value of the payment or other transfer of value, the date on which the payment or other transfer of value was provided to the covered recipient, the form of the payment or other transfer of value, the nature of the payment or other transfer of value, and the name of the covered drug, device, biological, or medical supply, as applicable.

The data base must contain information that is able to be easily aggregated and downloaded; including a description of any enforcement actions or penalties imposed on the reporting entity for violating the Sunshine reporting mandates during the preceding year[7], plus background information on industry-physician relationships. In the case of information submitted with respect to a payment or other transfer of value related to research, the data base must list such information separately from the other reported information and designate such separately listed information as funding for clinical research. HHS is granted authority to have the data base contain any other information helpful to the average consumer.

Reporting companies will be given an opportunity to review and submit corrections to the information submitted for at least 45 days prior to such information being made available to the public.

Under the federal "Sunshine" reporting requirements there is a broad preemption clause. As of January 1, 2012, when companies must begin tracking their interactions reportable under the federal reporting system, this federal law will preempt any state laws that require manufacturers to disclose or report the same type of information that is reportable to HHS.

However, the federal "Sunshine" reporting law does not totally preempt state reporting mandates. It does not preempt any state laws that require the disclosure or reporting of information that is not reportable to HHS or that cover a broader category of reporting parties or recipients than defined under the federal law.

The federal reporting system will not preempt any state laws that require the reporting of information that is exempt from reporting under the federal law (e.g. payments or transfers of value worth less than $10) but it will preempt state laws to the extent that they exempt payments or transfers of value worth $10 or more.

Furthermore, there is no preemption of state laws that require reporting to federal, state, or local governmental Agencies for public health surveillance, investigation, or other public health purposes or health oversight purposes.

For states like Massachusetts, that have already enacted reporting and gift bans laws regulating interactions between drug and medical device manufacturers and distributors and health care providers, the preemptive effect of the federal law must be analyzed

to understand the level of federal and state mandates regulated parties will need to follow starting in 2012.

An overview of this preemption analysis as it applies to the Massachusetts gift ban and public reporting law and the implementing Massachusetts Department of Public Health ("DPH") regulations [8] is set forth below.

I. Massachusetts Gift Ban

While federal health reform did eventually include the Physician Payment Sunshine Act reporting provisions that had been previously proposed by Senator Charles Grassley and others, it did not include any "gift ban" type restrictions on industry interactions with physicians and other health care providers.

Federal policy -- for now -- on the regulation of industry conflict of interest is not to enact a mandatory gift ban or code of conduct as some states, like Massachusetts and Vermont, have done. Instead, it embraces the mechanism of public disclosure as a means to bring to light those physicians who are entering into financial relationships with pharmaceutical and medical device companies that could be in conflict with their clinical, research and academic duties. [9]

Thus, state level regulation of industry interactions with physicians, hospitals and other providers through prohibitions and limits on payments is not preempted by the federal Sunshine reporting system.

In terms of the Massachusetts law this means that manufacturers and certain distributors must still adopt and comply with a compliance program and a Marketing Code of Conduct that conforms to the DPH regulations, 105 CMR 970.000,[10] and annually submit compliance plan information and certifications to DPH.

For instance, the Massachusetts limits on company gift giving to physicians – which is not a total gift ban as it permits certain educational items worth less than $100 – or the Massachusetts requirements for permissible consulting and other service relationships will not preempted. Conversely, the federal law will not alter the fact that Massachusetts law does not prohibit physicians from participating on company speaker's bureaus.[11]

Additionally, there is no preemption of the requirements under the DPH regulations that require pharmaceutical manufacturers and distributors to (i) comply with limitations and requirements on the use of non-patient identified prescriber data, including an "opt out" for physician and other prescribers on having their prescriber data used for marketing purposes, and (ii) obligate all contracted speakers and consultants who serve on a formulary or clinical guideline committees to disclose their company relationship to the committee.

Massachusetts, and other states, will continue to be able to pass state laws prohibiting and regulating interactions between industry and health care providers that do not involve governmental or public disclosure without any level of federal preemption.

II. Pre-2012 Massachusetts Reporting

State level governmental or public disclosure mandates, however, will be preempted starting with interactions and payments taking place in calendar year 2012. This means that states which already have laws that require disclosure to state agencies or to a public data base[12] may continue to operate those disclosure systems without any level of preemption through calendar year 2011.

Thus, the Massachusetts reporting system established under DPH's regulations is not preempted until 2012. This means that on July 1, 2010 (for the period July 1, 2009 through December 31, 2009) and on July 1, 2011 (for calendar year 2010) manufacturers and certain distributors are still required to disclose to DPH – for posting on its public website – the value, nature, purpose, and recipient of any sales and marketing activity payment, or other benefit, with a value of at least $50 to physicians (and other Massachusetts licensed professionals who are authorized to prescribe), hospitals, nursing homes, and pharmacists.

Of course, DPH could delay or modify its disclosure mandate and reporting system in reaction to the enactment of the federal Sunshine reporting system. But, the current DPH plan is to review the first batch of data submitted on July 1, 2010, and have the Massachusetts public data base "go live" some time in the fall of 2010.[13]

Companies are still required to pay an annual fee of $2,000 to DPH every July 1 through 2011. For 2012 and beyond, the scope of the federal preemption as to the DPH filing fee is not entirely clear.

III. Preempted Massachusetts Reporting

Starting in 2012 the federal "Sunshine" law preempts any state statute or regulation that requires

any entity that comes within the federal definition of "manufacturer" to disclose or report, in any format, the type of information reportable to HHS regarding payments or other transfers of value to physicians or teaching hospitals worth over $10.

Under the federal reporting system covered manufacturers will be required to track and report to HHS in their annual submissions the following data for each reportable payment or transfer of value:

(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 (the NPI will not be included in the public data base).

(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, indicated (as appropriate for all that apply) as—

(I) cash or a cash equivalent;
(II) in-kind items or services;
(III) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or
(IV) any other form of payment or other transfer of value (to be defined in HHS regulations).

(vi) A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

(I) consulting fees;
(II) compensation for services other than consulting;
(III) honoraria;
(IV) gift;
(V) entertainment;
(VI) food;
(VII) travel (including the specified destinations);
(VIII) education;
(IX) research;
(X) charitable contribution;
(XI) royalty or license;
(XII) current or prospective ownership or investment interest;
(XIII) direct compensation for serving as faculty or as a speaker for a medical education program;
(XIV) grant; or
(XV) any other nature of the payment or other transfer of value (to be defined in HHS regulations).

HHS is granted further authority to establish other categories of information that must be disclosed regarding each reportable payment or other transfer of value.

The federal reporting system will also require disclosure of the name of the drug, device, biological, or medical supply if the reportable payment or other transfer of value is related to marketing, education, research specific to a covered drug, device, biological, or medical supply. Once the HHS public data base goes on-line in 2013, the level of interactions by any physician or teaching hospital related to a certain drug or device will be more easily searchable.

Also, in the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient (e.g. a payment made to a charitable disease organization at the request of a physician), the applicable manufacturer is required to disclose that payment or other transfer of value under the name of the covered recipient.

The federal "Sunshine" reporting system will also require disclosure of any ownership or investment interests held by any physician (or immediate family member) in any group purchasing organization or "manufacturer" as defined under the federal law, other than interests in publicly traded securities or mutual funds.[14]

Beginning in 2012, the federal reporting law will preempt the Massachusetts DPH disclosure regulations to the extent they replicate the federal mandate. To the extent that any sales and marketing activity[15] interactions with Massachusetts physicians or teaching hospitals are reportable to HHS they no longer will be reportable to DPH.

Also, the broad reporting exemption established by DPH under the Massachusetts disclosure rules for clinical trials[16] and genuine research[17] will not apply to the federal reporting system. Starting in 2012 manufacturers will be required to track and report in the following year to HHS any payment or transfer of value worth $10 or more related to research or pre-market approval activities. However, such reported interactions do not become immediately public.

In the case of information submitted to HHS with respect to a payment or other transfer of value made pursuant to a product research or development agreement for services furnished in connection with research on a potential

new medical technology or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply, or in connection with a clinical investigation regarding a new drug, device, biological, or medical supply, such information, while reportable to HHS annually, will not be made immediately available on the public data base.

Such research related payments and transfers of value become public on the earlier of the FDA approval date or four calendar years after the date such payment or other transfer of value was made. During the non-public phase of such reported date, the information in the hands of HHS is not subject to the Freedom of Information Act.

IV. Non-Preempted Massachusetts Reporting

The Massachusetts disclosure system is broader in many respects compared to the new federal Sunshine reporting system. These aspects of the DPH rules will not be preempted and companies will still be required to track sales and marketing activities and file reports to DPH notwithstanding the commencement of the federal tracking and reporting requirements beginning in 2012.

For instance, while the federal law only require reports from distributors that are under common ownership with a manufacturer of a drug, device, biological, or medical supply, the Massachusetts disclosure mandate applies to independent distributors that take title (verses consignment) to products.

The Massachusetts definition of covered recipients of reportable interactions is also much broader than the federal system. While most payments and transfers of value to physicians, dental surgeons, podiatrists, optometrists, chiropractors and teaching hospitals will no longer be reportable to Massachusetts after 2011, companies will still be required to fully report all reportable sales and marketing activities under DPH's regulations made to other non-physician licensees who are authorized to precribe, non-teaching hospitals, nursing homes and pharmacists.

Also, the federal law exempts the following interactions from the public reporting system:

- product samples that are not intended to be sold and are intended for patient use (although the federal law will require separate non-public data base reporting to HHS);

- educational materials that directly benefit patients or are intended for patient use;

- the loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient;

- items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device;

- a transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient;

- discounts (including rebates);

- in-kind items used for the provision of charity care;

- a dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund;

- in the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan;

- in the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional; and

- in the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.

These federal exemptions are noteworthy because they are broader in many respects than the Massachusetts reporting exemptions. Yet under the rules of preemption the states can continue to require state reports of these types of transactions exempt from federal reporting. As one example, while payments to physicians for expert witness services will be categorically exempt from federal reporting, notwithstanding the enactment of the federal "Sunshine" reporting system companies subject to Massachusetts reporting will still have to continue

to determine whether such interactions come within the broadly ambiguous definition of "sales and marketing activity" under the DPH rules.

V. Other New Federal Transparency Requirements

Federal health reform has not only established a national reporting system for interactions between drug and device manufacturers and physicians and teaching hospitals, it also has established for the first time patient disclosure obligations on physicians.

The Stark Law is amended for services furnished on or after January 1, 2010, to require referring physicians, with respect to permitted referrals for magnetic resonance imaging, computed tomography, positron emission tomography, and any other Stark covered radiology services designated by CMS, to inform the patients in writing at the time of the referral that the patient may obtain the radiology services for which the patient is being referred from a person other than the referring physician, or his group practice and colleagues, and the patient must be provided with a written list of other suppliers who furnish such services in the area in which the patient resides.

In summary, these features of federal health reform, intended to shed light upon and mitigate possible conflicts of interest that could be unduly influencing physicians and other providers, will have a major impact on federal/state disclosure systems as well as patient access to information that previously was not public. Companies, physicians, hospitals and other parties regulated by these new federal provisions must be prepared to add them to their on-going efforts toward compliance.

1 Patient Protection and Affordable Care Act of 2009 (H.R. 3590, section 6002) which was signed into law on March 23, 2010, modified by the Health Care and Education Affordability Reconciliation Act of 2010
(the House Reconciliation package) signed into law on March 30, 2010.
2 See, Section 6002 of the Patient Protection and Affordable Care Act of 2009 entitled "Transparency Reports and Reporting of Physician Ownership or Investment Interests" which adds a new section to the United States Code, 42 U.S.C. §1128G.
3 Transfers of value worth less than $10 are not reportable unless the aggregate amount transferred to, requested by, or designated on behalf of the recipient by the manufacturer during a calendar year exceeds $100. These thresholds will be increased annually by the CPI.
4 "Manufacturer" is defined broadly to include any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply covered under Medicare, Medicaid, or Children's Health Insurance Program ("CHIP") (or any entity under common ownership with such entity which 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). Group purchasing organizations are also subject to the reporting requirements.
5 The law references the definition of physicians found in 42 U.S.C. §1395x(r) which includes dental surgeons, podiatrists, optometrists, chiropractors and physicians.
6 The first reporting submission date (for 2012 reportable payments) is March 31, 2013. Thereafter, the annual reporting date is the 90th day of each calendar year for reportable payments taking place the prior calendar year, with the past year's reported transactions added to the public data base each June 30.
7 Inadvertent violations of the federal reporting requirements can result in civil money penalties between $1,000 and $10,000 per non-reported transaction, up to $150,000 per year. Knowing violations can result in civil money penalties between $10,000 and $100,000 per non-reported transaction, up to $1 million per year.
8 Massachusetts General Law, Chapter 111N; Chapter 111N and implementing agency rules, DPH regulations 105 CMR 970.000.
9 Comments of Stephen Cha, MD, MHS, Professional Staff Member, Energy and Commerce Committee, US House of Representatives, Washington, DC, The Second National Disclosure Summit, March 4, 2010. See www.disclosuresummit.com.
10 The Massachusetts mandated Marketing Code of Conduct in many respects is more stringent than the standards set forth in the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, revised in July, 2008 and effective January 1, 2009, and the Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals, revised in December, 2008 and effective July 1, 2009. The Massachusetts mandated Marketing Code of Conduct also requires CME programs to adhere to the Accreditation Council for Continuing Medical Education ("ACCME") Standards for Commercial Support (even if ACCME accreditation is not secured).
11 Although Massachusetts law does not prohibit companies from hiring physicians to present at non-CME programs and meetings on a fair market value basis set forth in a written contract, (See, 105 CMR 970.008 2. a.), participation on a company speaker's bureau is increasingly becoming prohibited under conflict of interest policies adopted by academic medical centers, see e.g., Partners HealthCare Conflict of Interest Policy as described in the April 2009 Partners Commission on Interactions with Industry Report.
12 Massachusetts and Minnesota require disclosure to both a state agency and a public data base; the District of Columbia, Maine, Vermont and West Virginia require disclosure to a state agency.
13 Comments of Melisssa Lopes, Deputy General Counsel, Massachusetts Department of Public Health, The Second National Disclosure Summit, March 4, 2010. See www.disclosuresummit.com.
14 The exemption from this reporting requirement tracks the publicly traded company ownership and investment interest exception under the Stark Law.
15 "Sales and marketing activity" is defined under 105 CMR 970.004 as sales and marketing activities including "advertising, promotion, or other activity that is intended to be used or is used to influence sales or the market share of a prescription drug, biologic or medical device; to influence or evaluate the prescribing behavior of a covered recipient to promote a prescription drug , biologic, or medical device; to market a prescription drug, biologic, or medical device; or to evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force . . . [as well as] any product education, training, or research project that is designed or sponsored by the marketing division of a pharmaceutical or medical device manufacturing company or has marketing, product promotion, or advertising as its purpose."
16 105 CMR 970.009 states that reportable "sales and marketing "activity" does not include clinical trials and genuine research, particularly where the primary purpose is to generate data in support of an application filed with the FDA seeking approval for a new drug, biologic or medical device or "new use" or similar marketing or labeling claim requiring FDA approval. Clinical trials that are posted on clinicaltrials.gov will be deemed exempt from disclosure. "Clinical trial," is defined by 105 CMR 970.004 as "a genuine research project involving a drug or medical device that evaluates the safety or effectiveness of the particular drug, biologic or medical device in the screening, prevention, diagnosis, evaluation or treatment of a disease or health condition, or evaluates the safety or efficacy of the drug or medical device in comparison with other therapies, and which has been approved by the FDA and, if the trial involves volunteer human research subjects, it has been approved by a duly constituted Institutional Review Board ("IRB") after reviewing and evaluating it in accordance with the human subject protection standards set forth at 21 C.F.R. Part 50, 45 C.F.R. Part 46, or equivalent standards of another federal agency."
17 "Genuine Research Project" is defined under 105 CMR 970.004 as "a project intended to add to medical knowledge about the care and treatment of patients that constitutes a systematic investigation, designed to develop or contribute to generalizable knowledge when the results can be published by the investigator and reasonably can be considered to be of significant interest or value to scientists or health care practitioners working in the particular field of inquiry."