

Strafford

presents

Physician Payments Under PPACA's Sunshine Provisions and State Law

Meeting the Challenges of Healthcare Reform's Reporting Requirements

A Live 90-Minute Teleconference/Webinar with Interactive Q&A

Today's panel features:

Donald H. Romano, Partner, Moderator, **Arent Fox**, Washington, D.C.

Ann DesRuisseaux, Principal, **GlobalComplianceStrategies.com**, Dallas

Kathleen McDermott, Partner, **Morgan, Lewis & Bockius LLP**, Washington, D.C.

Wednesday, October 6, 2010

The conference begins at:

1 pm Eastern

12 pm Central

11 am Mountain

10 am Pacific

You can access the audio portion of the conference on the telephone or by using your computer's speakers.

Please refer to the dial in/ log in instructions emailed to registrants.

Health Industry Federal Transparency Requirements

Sec. 6002. Transparency Reports and Reporting of Physician Ownership or Investment Interests		
Provision Section of Social Security Act [U.S. Code citation]	DESCRIPTION OF REQUIREMENT	
1. Effective Date of Reporting Requirement § 1128G(a)(1)(A) [42 U.S.C. § 1320a-7g(a)(1)(A)]	Beginning March 31, 2013 and on the 90 th day of each calendar year thereafter (i.e., March 31 st), 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 [of HHS], in such electronic format as the Secretary shall require, information regarding any payments or transfers of value for the preceding calendar year.	
2. Procedures for Submission § 1128G(c)(1)(A)-(B) [42 U.S.C. § 1320a-7g(c)(1)(A)-(B)]	No later than October 1, 2011 , the Secretary [of HHS] will establish procedures for applicable manufacturers and applicable group purchasing organizations to submit required information to the Secretary [of HHS] and to make such information available to the public. These procedures shall provide, as appropriate, for the definition of terms not otherwise defined in the statute.	
3. Information that Must Be Reported Regarding Payments of Value § 1128G(a)(1)(A)(i)-(viii) [42 U.S.C. § 1320a-7g(a)(1)(A)(i)-(viii)]	<p>An applicable manufacturer must report the following information with respect to the preceding calendar year of any payment or other transfer of value to a covered recipient:</p> <ol style="list-style-type: none"> 1. The name of the covered recipient; 2. The business address of the covered recipient (and if the covered recipient is a physician, the specialty and National Provider Identifier of the covered recipient); 3. The amount of the payment or other transfer of value; 4. The dates on which the payment or other transfer of value was provided to the covered recipient; 5. A description of the form of the payment or other transfer of value, indicated as: <ul style="list-style-type: none"> • Cash or cash equivalent • In kind items or services • Stock, a stock option, or other ownership interest, dividend, profit, or other return on investment • Any other form of payment or other transfer of value, and 6. A description of the nature of the payment or other transfer of value, indicated as: <ul style="list-style-type: none"> • Consulting fees • Compensation for services other than consulting • Honoraria • Gift • Entertainment • Food • Travel • Education • Research • Charitable contribution • Royalty or license • Current or prospective ownership or investment interest • Compensation for serving as a faculty or as a speaker for a CME program • Grant 	

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		<ul style="list-style-type: none"> Any other nature of the payment or transfer of value
4.	<p>Additional Information to be submitted if payment is related to marketing, education, or research specific to a covered drug</p> <p>§ 1128G(a)(1)(A)(vii) [42 U.S.C. § 1320a-7g(a)(1)(A)(vii)]</p>	<p>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 applicable manufacturer also must provide the name of that covered drug, device, biological, or medical supply.</p>
5.	<p>Additional categories of information specified by the Secretary</p> <p>§ 1128G(a)(1)(A)(viii) [42 U.S.C. § 1320a-7g(a)(1)(A)(viii)]</p>	<p>An applicable manufacturer also must report any other categories of information regarding the payment or other transfer of value the Secretary [of HHS] determines appropriate.</p>
6.	<p>Payment or other transfers of value to an entity or individual at the request of a covered recipient.</p> <p>§ 1128G(a)(1)(B) [42 U.S.C. § 1320a-7g(a)(1)(B)]</p>	<p>If an applicable manufacturer provides a payment or other transfers of value to an individual or entity at the request of or designated by a covered recipient, the applicable manufacturer must disclose that payment or other transfer of value under the name of the covered recipient.</p>
7.	<p>Physician Ownership in Applicable Manufacturer</p> <p>§ 1128G(a)(2) [42 U.S.C. § 1320a-7g(a)(2)]</p>	<p>In addition to the requirements summarized above in rows #1 through #5, beginning March 31, 2013 and on the 90th day of each calendar year thereafter (i.e., March 31st), any applicable manufacturer or applicable group purchasing organization shall submit to the Secretary [of HHS], in such electronic format as the Secretary shall require, information regarding any ownership or investment interest (other than an ownership or investment interest in a publicly traded security or mutual fund) held by a physician (or an immediate family member of such physician) in the applicable manufacturer or applicable group purchasing organization during the preceding year.</p>
8.	<p>Information that must be Reported Regarding Ownership or Investment Interest</p> <p>§ 1128G(a)(2) [42 U.S.C. § 1320a-7g(a)(2)]</p>	<p>An applicable manufacturer or applicable group purchasing organization must report the following information with respect to the preceding calendar year of any ownership or investment interest held by a physician in the applicable manufacturer or applicable group purchasing organization:</p> <ol style="list-style-type: none"> The dollar amount invested by each physician. The value and terms of each ownership or investment interest. Any payment or other transfer of value provided to a physician holding such ownership or investment interest (or to an entity or individual at the request of or

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		<p>designated on behalf of the physician), including the information required under proposed new section 1128G(a)(1)(A)(i)-(viii) .</p> <p>4. Any other information regarding the ownership or investment interest the Secretary [of HHS] determines appropriate.</p>
<p>9.</p> <p>Penalties: Failure to Report § 1128G(b)(1) [42 U.S.C. § 1320a-7g(b)(1)]</p>	<p>Failure to submit the information required above may result in a CMP of not less than \$1,000 but not more than \$10,000 for each payment or other transfer of value or ownership or investment interest not reported.</p> <p>The total amount of CMPs imposed with respect to each annual submission shall not exceed \$150,000.</p>	
<p>10.</p> <p>Penalties: Knowing Failure to Report § 1128G(b)(2) [42 U.S.C. § 1320a-7g(b)(2)]</p>	<p>A knowing failure to submit the information required above may result in a CMP of not less than \$10,000 but not more than \$100,000 for each payment or other transfer of value or ownership or investment interest not reported.</p> <p>The total amount of CMPs imposed for knowing failures to report with respect to each annual submission shall not exceed \$1,000,000.</p>	
<p>11.</p> <p>Public Availability of Information § 1128G(c)(1)(C) [42 U.S.C. § 1320a-7g(c)(1)(C)]</p>	<p>No later than September 30, 2013, and on June 30 of each calendar year thereafter, the information required to be submitted will be made available to the public through an Internet website that:</p> <ol style="list-style-type: none"> 1. Is searchable and in a format that is clear and understandable; 2. Contains information that is presented by: <ul style="list-style-type: none"> • the name of the <u>applicable manufacturer</u> or <u>applicable group purchasing organization</u>, • the name of the <u>covered recipient</u>, • the business address of the <u>covered recipient</u>, • the specialty of the <u>covered recipient</u>, • the value of the <u>payment or other transfer of value</u> • the date on which the <u>payment or other transfer of value</u> was made to the <u>covered recipient</u>, • the form of <u>payment or other transfer of value</u>, • the nature of the <u>payment or other transfer of value</u>, and • the name of the <u>covered drug, device, biological, or medical supply</u>. 3. Can be easily aggregated and downloaded; 4. Describes any enforcement action taken, including CMPs; 5. Contains background information on industry-physician relationships; 6. Contains any other information the Secretary determines would be helpful to the average consumer; 7. Does not contain the National Provider Identifier of the <u>covered recipient</u>; and 8. Provides the <u>applicable manufacturer</u>, <u>applicable group purchasing organization</u>, or <u>covered recipient</u> an opportunity to review and submit corrections to the information listed for a period of not less than 45 days prior to such information being made available to the public. <p>For information related to payments made for product development agreements and</p>	

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		clinical investigations such information must be listed separately on the website and must designate such information as funding for clinical research.
12.	<p>Delayed Publication for Payments Made Pursuant to Product Research or Development Agreements and Clinical Investigations § 1128G(c)(1)(E) [42 U.S.C. § 1320a-7g(c)(1)(E)]</p>	<p>In the case of information submitted 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 the development of 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 shall be made available to the public on the first publication date after the earlier of the following:</p> <ul style="list-style-type: none"> • The date of the approval or clearance of the covered drug, device, biological, or medical supply by the FDA; or • Four calendar years after the date such payment or other transfer of value was made.
13.	<p>Annual Reports § 1128G(d)(1)-(2) [42 U.S.C. § 1320a-7g(d)(1)-(2)]</p>	<p>No later than April 1, 2013 (and on April 1 each year thereafter), the Secretary must submit a report to Congress that includes the information submitted for the preceding year aggregated for each applicable manufacturer or applicable group purchasing organization and a description of any enforcement actions taken.</p> <p>No later than September 30, 2013 (and on June 30 each year thereafter), the Secretary must submit a report to the States that summarizes the information submitted for the preceding year with respect to covered recipients in the State.</p>
14.	<p>Relationship with State Law § 1128G(d)(3) [42 U.S.C. § 1320a-7g(d)(3)]</p>	<p>Effective January 1, 2012, these transparency provisions will preempt any law or regulation of a state that requires an applicable manufacturer to disclose or report the type of information reported hereunder for payments or other transfers of value provided by the applicable manufacturer to a covered recipient.</p> <p>EXCEPTION: These transparency provisions do not preempt any law or regulation of a state that requires the disclosure or reporting of information -</p> <ul style="list-style-type: none"> • that is not required to be disclosed by these transparency provisions; • that is expressly excluded under 1128G(e)(10)(B) [see Row #15 below on exclusions]; • by any person or entity other than an applicable manufacturer or covered recipient; or • to a federal, state, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes. <p>The state preemption provisions are not to be construed to limit the discovery or admissibility of information in a criminal, civil, or administrative proceeding.</p>
15.	<p>Exclusions § 1128G(e)(10)(B) [42 U.S.C. § 1320a-7g(e)(10)(B)]</p>	<p>An applicable manufacturer shall not be required to submit information with respect to the following:</p> <ul style="list-style-type: none"> • A transfer of anything the value of which is less than \$10, unless the aggregate amount to a covered recipient during a calendar year exceeds \$100. For calendar years after 2012, the dollar amounts shall be increased by the same percentage increase in the consumer price index. • Product samples that are not intended to be sold and are intended for patient use. • Educational materials that directly benefit patients or are intended for patient use.

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Provision Section of Social Security Act [U.S. Code citation]	DESCRIPTION OF REQUIREMENT	
		<ul style="list-style-type: none"> • 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. • 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.
16.	Definition - Applicable Group Purchasing Organization § 1128G(e)(1) [42 U.S.C. § 1320a-7g(e)(1)]	A group purchasing organization 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.
17.	Definition - Applicable Manufacturer § 1128G(e)(2) [42 U.S.C. § 1320a-7g(e)(2)]	A 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.
18.	Definition - Clinical Investigation § 1128G(e)(3) [42 U.S.C. § 1320a-7g(e)(3)]	Any experiment involving 1 or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed or used.
19.	Definition - Covered Drug, Device, Biological, or Medical Supply § 1128G(e)(4) and (5)	Any drug, biological product, device, or medical supply for which payment is available under title XVIII [Medicare] or a State plan under title XIX [Medicaid] or XXI [SCHIP] (or a waiver of such a plan).

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	[42 U.S.C. § 1320a-7g(e)(4) and (5)]	
20.	Definition - Covered Recipient § 1128G(e)(6) [42 U.S.C. § 1320a-7g(e)(6)]	<ul style="list-style-type: none"> A physician (but does not include a physician employed by an applicable manufacturer). <p>The term "Physician" is defined by reference to Section 1861(r) of the Social Security Act and includes a doctor of medicine or osteopathy, a doctor of podiatric medicine, a doctor of optometry and a chiropractor.</p> <ul style="list-style-type: none"> A teaching hospital
21.	Definition - Payment or other transfer of value § 1128G(e)(10) [42 U.S.C. § 1320a-7g(e)(10)]	<p>A transfer of anything of value, but does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.</p> <p>Reporting is not required for the Exclusions provided in section 1128G(e)(10)(B).</p>

Summary of Other Transparency Requirements		
TOPIC Section of Social Security Act [U.S. Code citation]		DESCRIPTION OF REQUIREMENT
1.	Sec. 6001. Physician and Hospital Disclosures § 1877(i)(1)(C) [42 U.S.C. § 1395nn(i)(1)(C)]	<p>Requires hospitals to:</p> <ul style="list-style-type: none"> Submit annual reports to the Secretary [of HHS] containing a detailed description of each physician owner or investor (and any other owners or investors) of the hospital and the nature and extent of all ownership and investment interests. The Secretary [of HHS] will publish such information on the CMS website. Implement procedures requiring physician owners and investors to disclose to patients referred to the hospital the physician's ownership or investment interest. Disclose the fact that the hospital is partially owned or invested in by physicians on the hospital's public website and in any public advertising by the hospital. If the hospital admits a patient but does not have a physician on the premises during all hours in which the hospital will provide services to the patient, disclose to the patient, prior to admission, the limited physician availability. <p>The Secretary [of HHS] must implement policies and procedures for the above requirements within 18 months of enactment – the time at which the disclosure requirements begin.</p>

Summary of Other Transparency Requirements		
TOPIC	DESCRIPTION OF REQUIREMENT	
Section of Social Security Act [U.S. Code citation]		
2.	<p>Sec. 6003. Physician Disclosure Requirements for In-Office Ancillary Services § 1877(b)(2) [42 U.S.C. § 1395nn(b)(2)]</p>	<p>Requires that the regulations promulgated by the Secretary [of HHS] for the in-office ancillary services exception (under Sec. 1877(b)(2) of the SSA) include the following requirements for physicians who refer a patient for in-office radiology or imaging services:</p> <ul style="list-style-type: none"> • Inform the patient in writing at the time of the referral that the patient may obtain such services from a person other than the in-office provider, and • Provide the patient with a written list of suppliers who furnish such services in the area in which the patient resides. <p>Effective date: January 1, 2010.</p>
3.	<p>Sec. 6004. Prescription Drug Sample Transparency § 1128H [42 U.S.C. § 1320a-7h]</p>	<p>Requires manufacturers and authorized distributors of record to submit to the Secretary [of HHS] by April 1 of each year (beginning with 2012) the following information: the identity and quantity of drug samples requested and distributed, aggregated by the practitioner making the request. Reporting requirements begin on April 1, 2012.</p>
4.	<p>Sec. 6005. Pharmacy Benefit Managers Transparency Requirements § 1150A [42 U.S.C. § 1320b-21a]</p>	<p>Requires reporting by a health benefits plans or PBMs that manage prescription drug coverage under contract with:</p> <ul style="list-style-type: none"> • A PDP sponsor of a prescription drug plan or an MA organization offering an MA-PD plan under part D of title XVIII; or • A qualified health benefits plan offered through an exchange established by a State under section 1311 of the Patient Protection and Affordable Care Act. <p>Information to be reported to the Secretary [of HHS] includes:</p> <ul style="list-style-type: none"> • The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type, that is paid by the health benefits plan or PBM under the contract • The aggregate amount, and the type of rebates, discounts, or price concessions that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed. • The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed <p>PBMs also required to report the above information to the plan with which the PBM is under contract.</p> <p>No implementation date specified – reporting shall be “at such times, and in such form and manner, as the Secretary [of HHS] shall specify.”</p>
5.	<p>Sec. 6101. Nursing Homes – Required Disclosure of Ownership and Additional Disclosable</p>	<p>Requires nursing facilities and skilled nursing facilities to disclose information related to:</p> <ul style="list-style-type: none"> • Entities or individuals with ownership or control interests in the facility; • Members of the facility’s governing body; • Officers, directors, and other managing employees; • Individuals or entities that exercise operational, financial, or managerial control

Summary of Other Transparency Requirements	
TOPIC Section of Social Security Act [U.S. Code citation]	DESCRIPTION OF REQUIREMENT
<p>Parties Information § 1124(c) [42 U.S.C. § 1320a-3(c)]</p>	<p>over a facility;</p> <ul style="list-style-type: none"> • Individuals or entities that lease or sublease the real property to the facility; and • Individuals or entities that provide management or administrative services, management or clinical consulting, or accounting or financial services to the facility. <p>Beginning immediately, nursing facilities and skilled nursing facilities must keep and have available the above information until reporting regulations are implemented and the Secretary [of HHS] has made the reported information publicly available. The Secretary [of HHS] must issue final regulations on the reporting requirements within two years. Not later than 1 year after implementation of the final regulations, the Secretary [of HHS] must make the reported information publicly available.</p>
<p>6. Sec. 6106. Nursing Homes – Ensuring Staffing Accountability § 1128l(g) [42 U.S.C. § 1320a-7i(g)]</p>	<p>Requires nursing facilities to electronically submit to the Secretary [of HHS] direct care staffing information based on payroll and other verifiable and auditable data in a uniform format. Such information shall</p> <ul style="list-style-type: none"> • Specify the category of work a certified employee performs (such as whether the employee is an RN, LPN, etc.) • Include resident census data and information on resident case mix; • Include a regular reporting schedule; and • Include information on employee turnover and tenure and on the hours of care provided by each category of certified employees per resident per day. <p>The Secretary [of HHS] shall implement reporting requirements within 2 years. Reported information will be included in the Nursing Home Compare Website established pursuant to Sec. 6103 (Sec. 1819(i) of the SSA).</p>

STATE	REQUIREMENT
(CONT.)	<p>scholarship is chosen by the association sponsoring the conference or seminar.</p> <p>Manufacturers or labelers of prescription drugs must also submit an annual fee of \$1,000.</p> <p><i>Me. Stat. Ann. tit. 22, § 2698-A.3 – A.4.</i></p>
MASSACHUSETTS	<p><u>Reporting of Marketing Activities and Expenses.</u> Every pharmaceutical or medical device manufacturing company that employs a person to sell or market a drug, medicine, chemical, device or appliance in Massachusetts must disclose to the Department of Public Health July 1 of each year starting July 1, 2010 information on the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50, which the company provides, directly or through its agents, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, health care practitioner or other prescriber of drugs/devices in Massachusetts.</p> <p>Pharmaceutical or medical device manufacturing companies must also submit an annual fee of \$2,000, starting July 1, 2009.</p> <p><i>Mass. Gen. Laws ch. 111N, § 6.</i></p> <p><u>Marketing Code of Conduct.</u> The Department of Public Health will establish a Marketing Code of Conduct for drug/device manufacturing companies that is no less restrictive than the most recent versions of PhRMA’s and AdvaMed’s Codes on Interactions with Health Care Professionals. The code will prohibit:</p> <ol style="list-style-type: none"> (1) provision of or payment for meals for health care practitioners (“practitioners”) that: <ol style="list-style-type: none"> (a) are part of an entertainment or recreational event; (b) are offered without an informational presentation made by pharmaceutical marketing agent (“agent”) or without [agent] being present; (c) are offered, consumed, or provided outside of the practitioner's office or hospital setting; (d) are provided to a practitioner's spouse or other guest. (2) provision or payment of entertainment or recreational items of any value, including . . . tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any practitioner who is not a salaried employee of

STATE	REQUIREMENT
<p style="text-align: center;">MASSACHUSETTS (CONT.)</p>	<p>the company;</p> <p>(3) sponsorship or payment for continuing medical education . . . that does not meet the Accreditation Council for [CME] Standards For Commercial Support, or that provides payment directly to a practitioner;</p> <p>(4) financial support for the costs of travel, lodging or other personal expenses of non-faculty practitioners attending any CME event, third-party scientific or educational conference, or professional meetings, either directly to the individuals participating in the event or indirectly to the event's sponsor, except in cases as determined by the department;</p> <p>(5) funding to compensate for the time spent by practitioners participating in any CME event, third-party scientific or educational conferences, or professional meetings;</p> <p>(6) provision of or payment for meals directly at any CME event, third-party scientific or educational conferences, or professional meetings;</p> <p>(7) payments in cash or cash equivalents to practitioners either directly or indirectly, except as compensation for bona fide services;</p> <p>(8) any grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items to a practitioner in exchange for prescribing prescription drugs or using medical devices or for a commitment to continue prescribing prescription drugs or using medical devices.</p> <p>The code will allow:</p> <p>(1) provision, distribution, dissemination or receipt of peer reviewed academic, scientific or clinical information;</p> <p>(2) purchase of advertising in peer reviewed academic, scientific or clinical journals;</p> <p>(3) prescription drugs provided to a practitioner solely and exclusively for use by the practitioner's patients;</p> <p>(4) compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project or a clinical trial;</p> <p>(5) payment for reasonable expenses necessary for technical training on the use of a medical device if that expense is part of the vendor's purchase contract for the device.</p> <p>Every pharmaceutical or medical device manufacturing company that employs a person to sell or market a drug, medicine, chemical, device or appliance in Massachusetts is required to: (a) Adopt and comply with the most recent marketing code of conduct as adopted by the department; (b) Adopt a training program to provide regular training to appropriate employees including, without limitation, all sales and marketing staff, on the marketing code of conduct; (c)</p>

STATE	REQUIREMENT
<p>MASSACHUSETTS (CONT.)</p>	<p>Conduct annual audits to monitor compliance with the marketing code of conduct; (d) Adopt policies and procedures for investigating instances of noncompliance with the marketing code of conduct and take corrective action in response to noncompliance and the reporting of instances of noncompliance to the appropriate state authorities; and (e) Identify a compliance officer responsible for operating and monitoring the marketing code of conduct.</p> <p><i>Mass. Gen. Laws ch. 111N, §§ 2 and 4.</i></p> <p>Declaration for Marketing Code of Conduct. Every pharmaceutical or medical device manufacturing company that employs a person to sell or market a drug, medicine, chemical, device or appliance in Massachusetts shall disclose to the Department of Public Health annually by July 1 a declaration stating the following: (1) Description of its training program; (2) Description of its investigation policies; (3) Name, title, address, telephone number and electronic mail address of its compliance officer; and (4) Certification that it has conducted its annual audit and is in compliance with the marketing code of conduct.</p> <p><i>Mass. Gen. Laws ch. 111N, § 5.</i></p>
<p>MINNESOTA</p>	<p>Ban on Gifts. It is unlawful for any manufacturer or wholesale drug distributor, or any agent thereof, to offer or give any gift of value to a practitioner.</p> <p>Exemptions to this ban include the following: (1) Professional samples of a drug provided to a prescriber for free distribution to patients; (2) Items with a total combined retail value of not more than \$50; (3) A payment to the sponsor of a medical conference, professional meeting, or other educational program, provided the payment is not made directly to a practitioner and is used solely for bona fide educational purposes; (4) Reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting; (5) Compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project; (6) Publications and educational materials; and (7) Salaries or other benefits paid to employees.</p> <p><i>Minn. Stat. Ann. Sec. 151.461.</i></p> <p>Reporting of Payments to Practitioners. Wholesale drug distributors must report to the Board of Pharmacy annually</p>

STATE	REQUIREMENT
<p>MINNESOTA (CONT.)</p>	<p>by May 1 reports identifying all of the following types of payments, honoraria, reimbursement or other compensation from the preceding calendar year: (1) A payment to the sponsor of a medical conference, professional meeting, or other educational program, provided the payment is not made directly to a practitioner and is used solely for bona fide educational purposes; (2) Reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting; (3) Compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project. The report must include the nature and value of any payments totaling \$100 or more, to a particular practitioner during the year, and the identity of the practitioner. Reports filed under this provision are public data.</p> <p><i>Minn. Stat. Ann. Sec. 151.44 and 151.47.</i></p>
<p>NEVADA</p>	<p><u>Marketing Code of Conduct.</u> A wholesaler or manufacturer who employs a person to sell or market a drug, medicine, chemical, device or appliance in Nevada shall: (1) Adopt a written marketing code of conduct which establishes the practices and standards that govern the marketing and sale of its products; (2) Adopt a training program to provide regular training to appropriate employees, including, without limitation, all sales and marketing staff, on the marketing code of conduct; (3) Conduct annual audits to monitor compliance with the marketing code of conduct; (4) Adopt policies and procedures for investigating instances of noncompliance with the marketing code of conduct; and (5) Identify a compliance officer responsible for developing, operating and monitoring the marketing code of conduct.</p> <p><u>Disclosure of Code of Conduct.</u> A wholesaler or manufacturer who employs a person to sell or market a drug, medicine, chemical, device or appliance in Nevada must disclose to the Board of Pharmacy annually by June 1 the following: (1) A copy of its marketing code of conduct; (2) A description of its training program; (3) A description of its investigation policies; (4) The name, title, address, telephone number and electronic mail address of its compliance officer.; and (5) Certification that it has conducted its annual audit and is in compliance with its marketing code of conduct.</p> <p><i>Nev. Rev. Stat. §§ 639.570.1(a)-(e); Nev. Rev. Stat. §§ 639.570.2(a)-(e).</i></p>
	<p><u>Ban on Gifts to Practitioners.</u> It is unlawful for any drug, device or biologic manufacturer or wholesaler distributor of medical devices, or any agent thereof, to offer or give any gift to a healthcare provider. A “gift” is defined as (A) anything of value provided to a health care provider for free; or (B) any payment, food, entertainment, travel,</p>

STATE	REQUIREMENT
VERMONT	<p>subscription, advance, services, or anything else of value provided to a health care provider, unless it is an allowable expenditure or the health care provider reimburses the cost at fair market value.</p> <p>The general categories of allowable expenditures, all subject to detailed restrictions and requirements, include the following: (1) Payment to the sponsor of a significant educational, medical, scientific, or policy-making conference or seminar; (2) Honoraria and payment of expenses of a health care professional who serves on the faculty at such a conference or seminar; (3) Payment for a bona fide clinical trial; (4) Payment for a research project of scientific interest or value; (5) Payment or reimbursement of reasonable expenses necessary for technical training of health care professionals on the use of a medical device; (6) Royalties and licensing fees paid to health care providers for purchased patent rights or other intellectual property; and (7) Other reasonable fees, payments subsidies or other economic benefits provided by a manufacturer at fair market value</p> <p>The Vermont statute also identifies allowable gifts, subject to detailed restrictions and requirements. These allowable gifts include the following: (1) Samples given to a health care provider for free distribution to patients; (2) The loan of a medical device for a short-term trial period, not to exceed 90 days; (3) The provision of reasonable quantities of medical device demonstration or evaluation units; (4) The provision, distribution and dissemination of peer-reviewed scientific/medical/clinical journals or articles or other items that serve a genuine educational function; (5) Scholarships or other support for medical students, residents and fellows to attend a significant educational, medical, scientific, or policy-making conference or seminar; (6) Rebates and discounts; and (7) Labels approved by FDA for prescribed products.</p> <p><i>Vt. Stat. Ann. tit. 18, § 4631a.</i></p> <p>Reporting of Allowable Expenditures and Gifts. Every manufacturer of prescribed products are required to disclose to the Office of the Attorney General the name and address of the individual responsible for the company’s compliance with these requirements and allowable expenditures and gifts as defined above. Disclosures must be on a form provided by the Office of the Attorney General and must include the following: (1) the value, nature, and purpose of each allowable expenditure and gift; (2) the name of the recipient; (3) the recipient’s address; (4) the recipient’s institutional affiliation; (5) prescribed product or products being marketed, if any; and (6) the recipient’s state board number.</p> <p>The following expenditures/gifts are not required to be reported: (1) Royalties and licensing fees; (2) Rebates and discounts for prescribed products; (3) Certain payments for clinical trials, until the earlier of (i) the date the product is approved or cleared by FDA or (ii) two calendar years after the payment was made; and (4) Samples of a prescription</p>
VERMONT	

STATE	REQUIREMENT
(CONT.)	<p>drug provided to a health care professional for free distribution.</p> <p>For 2009, only drug manufacturers are require to report on the following dates: on or before July 1, for identifying the responsible person at the company, and on or before November 1 for disclosure of marketing activities (under old statutory requirements).</p> <p>For 2010 and thereafter, both drug and device manufacturers are required to report on the following dates: annually on or before July 1, for identifying the person at the company responsible for ensuring compliance with the reporting requirements, and annually on or before October 1 for disclosure of allowable expenditures and gifts.</p> <p><i>Vt. Stat. Ann. tit. 18, § 4632(a)(1)-(3).</i></p>
WEST VIRGINIA	<p><u>Reporting of Advertising Costs.</u> All manufacturers and labelers of prescription drugs dispensed in West Virginia that employ, direct or utilize marketing representatives must disclose to the West Virginia Pharmaceutical Cost Management Council annually on April 1 advertising costs for prescription drugs, based on aggregate national data, including all national aggregate expenses associated with advertising and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail and telephone communications as they pertain to residents of West Virginia.</p> <p>The following exemptions apply to this requirement: (1) All free samples of prescription drugs intended to be distributed to patients; (2) All payments of reasonable compensation and reimbursement of expenses in connection with a <i>bona fide</i> clinical trial; (3) All scholarship or other support for medical students, residents and fellows to attend significant educational, scientific or policy-making conference of national, regional or specialty medical or other professional association if the recipient . . . is selected by the association.</p> <p><i>W. VA. Code R. § 5A-3C-13(a)-(c).</i></p>