

# New York Law Journal



Web address: <http://www.nylj.com>

©2008 ALM Properties, Inc. An *incisivemedia* publication

VOLUME 240—NO. 90

THURSDAY, NOVEMBER 6, 2008

## OUTSIDE COUNSEL

BY ROBERT KIRBY, KARL H. BUCH AND PHOEBE A. WILKINSON

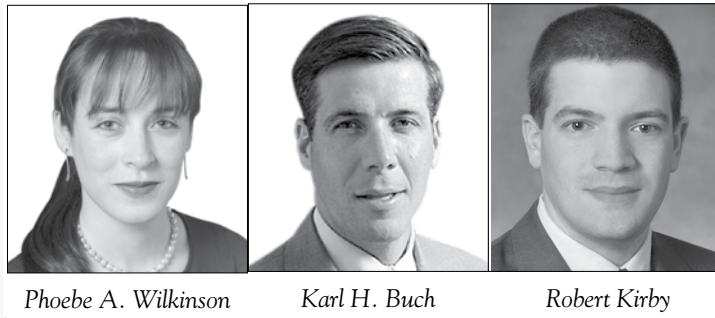
### *N.Y. Seeks to Join States Regulating Pay to Physicians*

Earlier this year, Governor David Paterson introduced a bill that would add New York to the growing number of states that have enacted legislation regulating payments, gifts, honoraria, and other items of value given to physicians by the pharmaceutical and/or medical device industries.<sup>1</sup>

Governor Paterson's stated intent in making this proposal is to "allow practitioners to exercise their clinical judgment and make prescribing decisions free of...influence." Some industry groups have voiced opposition to the governor's proposal, expressing concern that any such legislation would harm research and development and discourage manufacturers from doing business in New York.<sup>2</sup> Even if the governor's proposal becomes law, however, the federal Physician Payments Sunshine Act, currently making its way through Congress, might preempt it as well as comparable laws that have already been adopted in the District of Columbia, Maine, Massachusetts, Minnesota, Vermont, and West Virginia.<sup>3</sup>

#### **A Patchwork of State Legislation**

Pharmaceutical and medical device manufacturers already face a patchwork of state legislation mandating some form of



Phoebe A. Wilkinson

Karl H. Buch

Robert Kirby

disclosure for industry payments to physicians. Not surprisingly, even though these laws share a basic approach, they differ on a state-by-state basis with respect to (i) the type of information that must be disclosed, (ii) the public availability of such disclosures, (iii) the monetary thresholds that trigger disclosure, and (iv) the penalties for compliance failures. Governor Paterson's New York proposal, like the laws of other states such as Massachusetts and Minnesota, goes further than most of these laws: not only would it require disclosure of certain industry payments to physicians, but it would entirely prohibit others.

- **West Virginia.** West Virginia's law is regarded as one of the least onerous; pharmaceutical manufacturers<sup>4</sup> disclosures are limited to their "national aggregate expenses associated with advertising and direct promotion of prescription drugs...as they pertain to residents" of West Virginia,<sup>5</sup> and such manufacturers need not disclose information regarding individual payments to individual physicians. Any "national aggregate expense [information]" disclosed to state officials is considered confidential and is not subject to release under West Virginia's Freedom of Information Act.<sup>6</sup> Further, West Virginia's statute does not impose penalties or any enforcement mechanism on manufacturers for failure to comply.

- **District of Columbia, Maine, Vermont.** The District of Columbia, Maine and Vermont each require greater disclosures from

pharmaceutical manufacturers<sup>7</sup> than West Virginia. In each of those jurisdictions, manufacturers must disclose information regarding individual payments to individual physicians. The monetary threshold for such disclosures is relatively low, manufacturers must disclose any payments to a physician the value of which exceeds \$25.

In both the District of Columbia and Maine, information disclosed by manufacturers pursuant to the statutes is treated as confidential.<sup>8</sup> Vermont's law, while not stating that disclosures are confidential per se, contains a widely employed exception that allows manufacturers to "protect" trade secrets.<sup>9</sup> Indeed, a recent study reported in the *Journal of the American Medical Association (JAMA)* found that 61 percent of payments to physicians that had been disclosed under the Vermont law were designated "trade secrets" by the reporting manufacturer, and were therefore kept confidential from the public.<sup>10</sup>

With respect to penalties for violations of the respective states' disclosure requirements, the District of Columbia and Maine statutes provide for penalties of up to \$1,000 per violation, while the Vermont statute provides for penalties of up to \$10,000 per violation.<sup>11</sup>

- **Minnesota.** With respect to Minnesota's statute requiring disclosure of individual payments to individual physicians, the threshold is higher—manufacturers must disclose all payments exceeding \$100. However, the previously referenced study suggested that a majority of payments made to physicians may fall below this higher threshold, and therefore do not have to be disclosed.<sup>12</sup>

In addition to its disclosure requirements, Minnesota's statute goes a step further: it adopts an outright *prohibition* on "gifts" to

---

**Robert Kirby** is a law clerk in Chadbourne & Parke LLP's litigation department. **Karl H. Buch** is litigation counsel with the firm. **Phoebe A. Wilkinson** is a litigation partner with Chadbourne. **Matthew DellaValle**, a 2008 summer associate, assisted with the preparation of this article. They are reachable at 212-408-5100 or [kbuch@chadbourne.com](mailto:kbuch@chadbourne.com) and [pwilkinson@chadbourne.com](mailto:pwilkinson@chadbourne.com)

physicians,<sup>13</sup> although notably, the definition of “gifts” excludes patient samples, honoraria, services in connection with a genuine research project, publications and educational materials, and items with a combined value of less than \$50 per year.

With respect to public access to such information, while Minnesota’s statute unequivocally considers any disclosures “public data,”<sup>14</sup> the state has set up a system rendering such information extremely difficult to obtain. Pursuant to this system, only “[t]he original individual payment disclosure forms are made available,” and only to those members of the public willing to “travel to the state office in Minnesota in order to photocopy each form at a fee of \$0.25 per copy.”<sup>15</sup>

• **New York.** Governor Paterson’s proposal, introduced in the state Assembly on May 21, 2008 (A.11187) is stricter still. It would prohibit pharmaceutical and medical device manufacturers from giving physicians payments or gifts with a monetary value in excess of \$50 per year.<sup>16</sup> While there are exclusions—samples of prescription medications; payments in connection with bona fide research, clinical, or educational activity; discounts; certain travel expenses; and payments to relatives are not prohibited—the payment for such permissible items must still be disclosed to the state on an annual basis in a form that specifies the fair market value of the benefit, and the nature of any services provided to the manufacturer by the recipient in connection with the payment. Governor Paterson’s proposal would also require manufacturers to disclose any financial relationships they have with physicians if those relationships exceed a particular dollar threshold.

Manufacturers who fail to comply would face penalties of between \$5,000 and \$50,000 per violation. And, information about disclosures made pursuant to the New York law would be available to the public.

• **Massachusetts.** On Aug. 10, 2008, Massachusetts became the most recent state to adopt a disclosure law.<sup>17</sup> Like Governor Paterson’s New York proposal, the Massachusetts law prohibits several categories of payments to physicians. But unlike Governor Paterson’s proposal, the Massachusetts law directs its state department of health to “adopt a standard marketing code of conduct” with which

all pharmaceutical and medical device manufacturers must comply. The statute further directs that the Massachusetts Department of Health adopt regulations “no less restrictive” than the voluntary industry codes of conduct promulgated by the Pharmaceutical Researchers and Manufacturers of America (PhRMA) and the Advanced Medical Technology Association (AdvaMed).<sup>18</sup>

Further, the Massachusetts law states that the code of conduct to be established must prohibit, inter alia, manufacturer payments for (i) meals for physicians (or their guests) at entertainment or recreational events, (ii) recreation or entertainment items (e.g., sporting event tickets, sporting equipment, vacations), (iii) certain continuing medical education programs, and (iv) grants, scholarships, or educational- or practice-related items provided in exchange for prescribing medications or using medical devices. Notably, however, the statute mandates that the code of conduct must permit,

---

*Governor Paterson’s stated intent in making this proposal is to “allow practitioners to exercise their clinical judgment and make prescribing decisions free of... influence.”*

---

inter alia, manufacturer payments for (i) product samples for patients, (ii) services rendered in connection with a research project or clinical trial, and (iii) technical training on the use of a medical device if the training is associated with the purchase contract for the device.

Pursuant to the Massachusetts law, any payment or other economic benefit with a monetary value of \$50 or more must be disclosed in an annual report to the Massachusetts Department of Health.<sup>19</sup> The statute authorizes penalties of up to \$5,000 per violation for failure to comply.<sup>20</sup> And, the Massachusetts Department of Health is required to make the disclosures publicly available on a searchable Web site.

## Federal Sunshine Act

The stated goal of the federal Physician Payments Sunshine Act (PPSA) is to shine “sunlight” on industry payments to physicians, as opposed to limiting them outright. Senator Grassley, R-Iowa, one of the sponsors of the PPSA, has explained that the rationale behind the legislation is to bring “transparency” to such payments and to “foster accountability by empowering consumers and other watchdogs.”<sup>21</sup>

• **Competing Versions of the Act.** The PPSA was first introduced in the Senate (S.2029) on Sept. 6, 2007. On March 13, 2008, the House introduced another version (H.R.5605).<sup>22</sup> Both versions would require manufacturers of covered<sup>23</sup> medications, medical devices, or medical supplies to file reports with the secretary of Health and Human Services detailing certain individual payments or other transfers of value that have been made to individual physicians. And, pursuant to both, it is intended that such disclosures would then be made available to the public on a searchable Web site.

Both the Senate and House bills are currently in committee. The Senate bill has recently gained the support of industry groups including AdvaMed and PhRMA, as well as from several large medical device and pharmaceutical manufacturers including AstraZeneca, Eli Lilly & Co., Johnson & Johnson, Medtronic Inc., Merck & Co., and Zimmer Inc.<sup>24</sup> Such industry support came about after legislators agreed earlier this summer to revise the Senate bill to address certain industry concerns.<sup>25</sup>

As revised, the Senate bill would now require disclosure, on an annual basis, of payments or transfers of value to physicians, including money, food, entertainment, gifts, travel, consulting fees, and honoraria. The Senate bill would exempt from disclosure certain transfers of value to physicians including product samples for patients, discounts and rebates, and certain educational materials and training. While the Senate bill would apply to all pharmaceutical and medical device manufacturers, the House bill would exempt manufacturers with annual revenues of less than \$1 million. Unlike the House bill, the revised Senate bill’s reporting requirements would be triggered only when specified monetary thresholds are exceeded.

Individual transfers of value would not need to be reported if their monetary value is less than \$25 and no transfers of value to a given physician would need to be disclosed if they do not exceed \$500 in the aggregate for that year.<sup>26</sup>

Under the Senate bill, violations of the reporting requirements would be punishable by penalties of \$1,000 to \$5,000 per violation, and the penalties would increase to \$5,000 to \$50,000 for knowing violations. Significantly, the revised Senate bill would provide for a cap on a violator's annual penalties in the amount of \$250,000 for knowing violations and \$50,000 for other violations. Although these caps are larger than the more modest penalties prescribed by the various state statutes, it should be noted that none of the state statutes provide for any annual limit on total penalties. Moreover, penalties under the revised Senate bill would be lower than those prescribed by the House bill, which would authorize penalties of \$10,000 to \$100,000 per knowing violation, with no annual cap.

Under the revised Senate bill, implementation of disclosure requirements would be delayed until March 31, 2011. Conversely, the House bill calls for implementation on Jan. 1, 2009.

• **Preemption Under the Senate Bill.**

Perhaps the most significant revision to the Senate bill is that it would now expressly provide for preemption of state reporting requirements. Such a promise of preemption should lessen industry worries about compliance with "[a] patchwork of 50 State laws," requiring disclosure of different information, in different formats, and at different times.<sup>27</sup> However, because the precise scope of the proposed preemption is unknown, it is uncertain exactly how passage of the PPSA would affect the diverse proposed and current state laws regulating industry payments to physicians. The laws of the District of Columbia, Maine, Vermont, and West Virginia, for example, which require disclosure without limiting the payments themselves, would appear to be preempted by the passage of the PPSA.

The issue of preemption may be less straightforward, however, with respect to Governor Paterson's proposal for New York and the laws of Minnesota and Massachusetts, which contain outright prohibitions against certain industry payments.

## Conclusion

The PPSA's proposed establishment of a single federal reporting system for payments to physicians could simplify both industry compliance and interested consumers' access to information. It remains to be seen, however, whether and to what extent the final PPSA would preempt state laws that, like the law proposed by Governor Paterson in New York, expressly prohibit certain industry payments to physicians.



1. Press Release, Governor David A. Paterson, "Governor Paterson Proposes Legislation to Reduce Improper Influence in Drug Prescription" (May 15, 2008), available at [http://www.ny.gov/governor/press/press\\_0515085.html](http://www.ny.gov/governor/press/press_0515085.html).

2. E.B. Solomont, "Fight Erupts Over Bill on Gifts to Doctors," N.Y. Sun, June 18, 2008.

3. D.C. Code §48-833.01; Me. Rev. Stat. tit. 22, §2698-A; Minn. Stat. §151.47; Vt. Stat. tit. 18, §4632; W. Va. Code §5A-3C-13; Mass. Gen. Laws ch. 111N, §§1-7 (effective Jan. 1, 2009).

4. West Virginia's law applies to pharmaceutical manufacturers only and not manufacturers of medical devices.

5. W. Va. Code. §5A-3C-13(b).

6. W. Va. Code. §5A-3C-13(e); see generally W. Va. Code §29B-1-1.

7. Like the West Virginia statute, the disclosure laws in the District of Columbia, Maine and Vermont apply to pharmaceutical manufacturers and not manufacturers in the medical device industry.

8. D.C. Code §48-833.05; Me. Stat. §2698-A(7).

9. Vt. Stat. tit. 18, §4632(a)(3).

10. Joseph S. Ross et al., "Pharmaceutical Company Payments to Physicians: Early Experiences With Disclosure Laws in Vermont and Minnesota," 297 JAMA No 11, at 1216 (March 21, 2007).

11. D.C. Code §48-833.06; Me. Stat. §2698-A(8); Vt. Stat. Ann. tit. 18, §4632(b). In Minnesota, the failure to comply with disclosure requirements may result in the manufacturer's loss of its wholesale drug distributor license. Minn. Stat. §151.47(b).

12. See Ross, *supra* note 10, at 1220 (noting that in Vermont, which has a \$25 reporting threshold, "77 percent of publicly disclosed payments were for less than \$100").

13. Minn. Stat. §151.461.

14. Minn. Stat. §151.47(f).

15. Ross, *supra* note 10, at 1218.

16. N.Y. Assembly Bill 11187 (May 21, 2008).

17. Massachusetts' law applies to manufacturers in both the pharmaceutical and medical device industries.

18. *Id.* See also PhRMA Code on Interactions with Healthcare Professionals (revisions effective Jan. 1, 2009), available at [http://www.phrma.org/code\\_on\\_interactions\\_with\\_healthcare\\_professionals](http://www.phrma.org/code_on_interactions_with_healthcare_professionals); AdvaMed Code of Ethics on Interaction with Health Care Professional (revised April 15, 2005), available at <http://www.advamed.org/memberportal/about/code>. Similarly,

California requires pharmaceutical and medical device manufacturers to adopt their own compliance programs that conform with PhRMA's code. Cal. Health & Safety Code §119402.

19. Mass. Gen. Laws ch. 111N, §6 (effective Jan. 1, 2009).

20. Mass. Gen. Laws ch. 111N, §7 (effective Jan. 1, 2009).

21. Senators Welcome Endorsements from PhRMA, AdvaMed of Physician Payments Sunshine Act, Dow Jones Factiva, May 22, 2008.

22. Physician Payments Sunshine Act of 2007, S.2029, 110th Cong. (1st Sess. 2007); Physician Payments Sunshine Act of 2008, H.R.5605 (2nd Sess. 2008).

23. Application of the PPSA is technically limited to manufacturers of drugs, devices, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.

24. Senators Welcome Endorsements from PhRMA, AdvaMed of Physician Payments Sunshine Act, Dow Jones Factiva, May 22, 2008; Benedict Carey, Drug Maker to Report Fees to Doctors, Sept. 25, 2008.

25. Press Release, Senate Special Committee on Aging, "Senators Praise Growing Support for Transparency in Drug Industry Payments to Physicians" (May 13, 2008) (summarizing revisions to S.2029), available at <http://www.aging.senate.gov/record.cfm?id=297721>.

26. If transfers of value to a particular physician fall within these guidelines, then the name of the recipient, the recipient's city and state, the value of the transfer, the date of the transfer, and the form and reason for the transfer must be disclosed.

27. Hearing before the Senate Special Committee on Aging, 110th Cong. (Feb. 27, 2008) (written testimony of Christopher L. White, Executive Vice President, General Counsel, and Secretary of AdvaMed), available at <http://www.advamed.org/MemberPortal/Issues/Comments>.

Reprinted with permission from the November 6, 2008 edition of the New York Law Journal © 2008 ALM Properties, Inc. All rights reserved. Further duplication without permission is prohibited. For information, contact 877-257-3382 or [reprintscustomerservice@incisivemedia.com](mailto:reprintscustomerservice@incisivemedia.com). ALM is now Incisive Media, [www.incisivemedia.com](http://www.incisivemedia.com). # 070-11-08-0008

CHADBOURNE  
& PARKE LLP

[www.chadbourne.com](http://www.chadbourne.com)