

## Client Alert

### April 2010

**Disclosure of financial ties between physicians and companies has finally been universally mandated as part of the recently passed health care bill, officially known as the Patient Protection and Affordable Care Act of 2010 (“the Act”).<sup>1</sup> This CLIENT ALERT discusses the Physician Payments Sunshine Provision (“Sunshine Provision”) found within the Act.<sup>2</sup> The Sunshine Provision was originally introduced in 2007 by Senator Chuck Grassley (R-Iowa), and was debated vigorously before recently becoming law. Now the Sunshine Provision is law and it will go into effect on March 31, 2013. The Act mandates strict disclosure requirements for companies and harsh penalties for non-compliance. Below is a summary of key elements of the Sunshine Provision and what it requires of our industry.**

#### **PHYSICIAN PAYMENTS SUNSHINE PROVISION**

The Act requires companies to begin reporting “transfers of value” worth more than \$10 no later than March 31, 2013.<sup>3</sup> That is, things like gifts or consulting payments made by companies in 2012 must be reported no later than March 31, 2013. Thus the law only gives companies about a year and a half to develop and implement internal tracking procedures. The government plans to take the disclosed information and enter it into a searchable database containing the names and addresses of each physician recipient and the details of the payments. Current plans make this database available to the public by September 30, 2013, and by June 30 each year thereafter. Notably there is no exemption for small companies as was discussed previously in debates leading up to the enactment of the law. It has yet to be determined whether the Sunshine Provision will pre-empt state laws. Our belief is that more rigid state laws (like Vermont’s and Massachusetts’) will remain in place in addition to requirements created by the Sunshine Provision contained with the Act.

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<sup>1</sup> The Sunshine Provisions can be found at Section 6002 of the Act.

<sup>2</sup> Pub. L. No. 111-148.

<sup>3</sup> The Act requires companies to track and report items if they are a medical device or pharmaceutical manufacturer that is engaged in the production, preparation, propagation, compounding or conversion of a drug, device, biological or medical supply, or any entity under common ownership with such medical device or pharmaceutical manufacturer that provides assistance or support to the manufacturer with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a drug, device, biological, or medical supply.

## What Must Be Reported Under the Sunshine Provision

The Act requires companies to report anything of value provided to physicians, and specifically references the following:

- Gifts,
- Entertainment,
- Travel expenses,
- Consulting fees,
- Research funding or grants,
- Honoraria,
- Charitable contributions,
- Educational funding,
- Direct compensation provided to faculty members of educational seminars,
- Collaborative research,
- Ownership or investment interest held by physician in company,
- Royalties,
- Licensing fees,
- Dividends,
- Profit distribution,
- Stock or stock option grants, and
- Additions the Secretary of Health & Human Services (“the Secretary”) deems appropriate.

## Exclusions from Reporting

The Act excludes the following:

- A transfer of anything of value < \$10 (unless aggregate amount > \$100 in a calendar year),
- Product samples,
- Educational materials for the benefit of patients,
- Loans of medical device models for no more than 90 days,<sup>4</sup>
- Warranties (for replacement devices),
- Discounts or cash rebates,
- Gifts made to doctors who work for the company in question,
- Items received for free as a patient,<sup>5</sup>
- In-kind items used for the provision of charity care, and
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund.<sup>6</sup>

## Reporting Thresholds

The Act also requires companies to report any payments to physicians if the physician receives more than \$100 annually. For example, if a physician were to receive twenty-one \$5 meals within a calendar year, the company would have to report each “transfer of

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<sup>4</sup> To permit evaluation of the covered device by the covered recipient.

<sup>5</sup> Doctor cannot be acting in the professional capacity of a covered recipient.

<sup>6</sup> Described in section 1877(c).

value” because the total was \$105 over the course of a year. According to the statute, even a \$0.25 pencil would need to be reported if the total exceeded \$100 within a year.<sup>7</sup>

## **Penalties**

Penalties for **inadvertent** non-compliance (e.g. failure to report payments over \$10 or all payments in excess of \$100 per year) include civil fines range from \$1000 to \$10,000 per occurrence. For example, if a company made eleven consulting payments of \$500 each to a physician and failed to report any of them because it was not aware of the new law, the company could be fined up to \$110,000 by the government. Non-intentional violations are capped at \$150,000 per year.

Companies found to have “**knowingly**” avoided reporting can face harsher penalties. Civil fines for “knowingly” violating the statute range from \$10,000 to \$100,000. The cap on fines is \$1,000,000 per year for knowingly violating the statute.

## **What Comes Next**

### October 1, 2011:

- Reporting procedures established.
- Details provided on what exactly will be made public.

### January 1, 2012:

- Companies begin recording physician payments and physician ownership interests.

### March 31, 2013:

- By this date, companies must report physician payments and physician ownership interests to the Secretary for the first time.

### September 1, 2013 (and every June 30 thereafter):

- Disclosed information published by the Secretary to the internet for public viewing.

## **CONCLUSION**

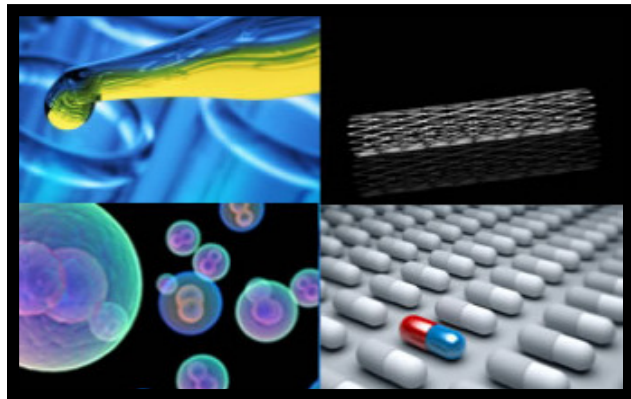
DuVal & Associates will be monitoring implementation of the Sunshine Provision. Many of the details will be worked out in coming months with additional regulation. DuVal & Associates will keep you abreast of the situation. Stay tuned to [www.duvalfdalaw.com](http://www.duvalfdalaw.com) for updates.

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<sup>7</sup> Such a gift would of course be illegal in states where gifts are banned.

## **CALL ON US FOR ASSISTANCE WITH YOUR REGULATORY NEEDS**

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