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## Health Care Reform Includes Significant Transparency and Disclosures Initiatives

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On March 25, the House gave final approval to the budget reconciliation bill, which contained changes to the Patient Protection and Affordable Care Act (the ''Act'; Pub. L. 111-148) as passed by the Senate in December 2009 and the House on March 21, and was signed into law by President Obama on March 23. [The reconciliation bill, the Health Care and Education Reconciliation Act of 2010, was signed March 25 and became Pub. L. 111-152.]

The passage of the reconciliation bill represents the end of the legislative battle by Democrats to pass a health care reform bill. The Act includes significant new transparency and disclosure obligations that apply to physicians, hospitals, and medical device and pharmaceutical manufacturers.

Some of these transparency and disclosure obligations are based on legislation introduced by Sens. Chuck Grassley (R-Iowa) and Herb Kohl (D-Wis.), which was previously entitled ''the Physician Payments Sunshine Act of 2009.'' The transparency and disclosure obligations have been included in the Act in an effort to reign in costs of expanded health care availability.

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The premise behind the obligations is that ''sunshine'' on physician's financial relationships with industry will reduce conflicts of interest by deterring industry from spending excessive amounts of money on such relationships and consequently reduce the negative impact such relationships have on prescribing practices.

This article provides a brief overview of several of the transparency and disclosure obligations that are included in the Act.

1. *Physician Hospital Ownership Disclosure*. The Act contains significant new restrictions on physician ownership of hospitals. Under the Act, construction of new physician-owned hospitals is limited to those which will have earned Medicare certification by August 2010—the reconciliation bill extends this deadline to Dec. 31, 2010. This December 2010 cut-off represents a 10-month extension beyond the initial proposed deadline of February 2010. In addition to limiting construction of new physician-owned hospitals or expansion of existing physician-owned hospitals, the Act imposes reporting obligations for each hospital that is owned in whole or in part by physicians. Under the Act, such hospitals must submit an annual report describing the identity of each physician, owner, and investor and the nature and extent of all ownership investment interests in the hospital.[1] This information will be published on a public internet website maintained by the Centers for Medicare & Medicaid Services (''CMS'').

2. *Medical Device and Pharmaceutical Manufacturers*. Beginning March 31, 2013, and every year thereafter, any applicable pharmaceutical or medical device manufacturer is required to make annual disclosures

[1] *See* Section 6001.

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concerning payments to physicians and certain other providers.[2] Under the Act, applicable manufacturers must report certain types of payments or other transfers of value to physicians and teaching hospitals. The report will need to include the name and address of the recipient, the amount of payments or other transfer of value, and a description of the form and nature of the payment. Under the Act, payments or other transfers of value that require disclosure include consulting fees, compensation for services, honoria, gifts, entertainment, food, travel, and a variety of other grants and other consideration that may be given to physicians and teaching hospitals. In addition to reporting these gifts and transfers of value, beginning March 31, 2013, and every year thereafter, pharmaceutical and medical device manufacturers and applicable group purchasing organizations will be required to disclose any and all ownership held by a physician in the company. Failure to submit the required information may result in a Civil Monetary Penalty 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.

3. *In-Office Ancillary Services Disclosures*. Physicians are generally permitted to provide a variety of Designated Health Services (''DHS'') from their practice setting pursuant to the in-office ancillary services exception to the Stark Act. The Act does not require a disclosure to CMS or any other regulatory body regarding the provision of such services. However, the Act does include a requirement that physicians inform patients in writing at the time of a referral for such services, that the patient may obtain these services from a person other than the physician who owns the machines.[3] This applies to MRI, CT, PET and any other DHS that the Secretary of the Department of Health and Human Services (''DHHS'') determines appropriate. This amendment to the Social Security Act is effective as of Jan. 1, 2010.

4. *Prescription Drug Sample Transparency*. The Act requires manufacturers and authorized distributors of pharmaceuticals to report to the HHS Secretary the identity and quantity of drug samples requested and the identity and quantity of drug samples actually distributed.[4] The report must include the name, address, professional designation, and signature of the practitioner that makes the request. The first report is due on April 1, 2012, and subsequent reports are due on April 1 of each year thereafter. The Act does not include any requirement that CMS process or disclose this information.

5. *Pharmacy Benefit Managers Transparency*. The Act requires that pharmacy benefit managers (''PBM'') provide DHHS with certain information including the percentage of all prescriptions that were provided through mail order pharmacies as opposed to retail pharmacies and the percentage of prescriptions for which a generic drug was available and dispensed.[5] PBMs serve as the middlemen between health insurance plans, pharmaceutical manufacturers, and pharmacies. The measure is intended to create transparency into the discounts achieved by PBMs. The reporting requirements applies to health benefits plans or any entity that provides pharmacy benefits management services on behalf of a health benefits plan that manages prescription drug coverage under contract with (1) a prescription drug plan sponsor of a prescription drug plan or an Medicare Advantage organization offering a Medicare Advantage prescription drug plan under Medicare Part D; or (2) a qualified health benefits plan offered through a health insurance exchange established under the Act. In addition to mail order and generic information, PBMs are also required to disclose the aggregate amount and type of rebates, discounts or price concessions that are attributable to patient utilization under the plan. Further, PBMs are required to disclose the aggregate amount of rebates, discounts or price concessions that are passed through to the plan sponsor and the total number of prescriptions that were dispensed. The report would exclude bona fide service fees such as distribution service fees, inventory management fees, and fees associated with administrative service agreements and patient care programs. Finally, PBMs would be required to disclose the aggregate amount of the difference between the amount the health benefit plan pays the PBM and the amount that the PBM pays retail pharmacies and mail order pharmacies, as well as the total number of prescriptions that were dispensed. This information would be held confidential and not disclosed by the DHHS.

These new transparency and disclosure initiatives included in the Act signal the beginning of a new era of federal government oversight of the healthcare system. Up until now, the states have been leading the charge on the regulation of physician relationships with industry. Several states, including Minnesota, Massachusetts, and Vermont have passed their own transparency and/or disclosure laws. With government health care expenditures under the health care reform law estimated to be close to $1 trillion over the next 10 years, and increasing compliance challenges with the growing patchwork quilt of state legislation, it is now certain that there will be increased federal vigilance and oversight over the financial influences in the health care system.

[2] *See* Section 6002.
[3] *See* Section 6003.
[4] *See* Section 6004.
[5] *See* Section 6005.

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