

Healthcare Reform Law Delivers New Transparency Requirements for the Health Industry

March 29, 2010

The Patient Protection and Affordable Care Act of 2010 as amended by the Health Care and Education Reconciliation Act of 2010 (the Healthcare Reform Law) provides for a number of new transparency requirements for several health industry sectors, including drug and device manufacturers and suppliers, pharmacy benefit managers, physician practices that provide ancillary services, and skilled nursing facilities. These requirements are generally related to financial relationships and activities and impose mandatory reporting obligations to the government that will have a broad impact on internal tracking and monitoring procedures as well as industry funding activities related to research, training, and education.

The different effective dates and the complexity of the various transparency requirements, as well as the need for agency definitional and process guidance, will require vigilant monitoring of agency implementation efforts. Health industry sectors should be aware of rule-making notice and comment opportunities and consider offering guidance and perspective as these new standards evolve.

The transparency requirements in Section 6002 of the Healthcare Reform Law (previously known as the Physician Payment Sunshine Act) illustrate the complexity and broad impact of these transparency requirements. Section 6002 applies to device, drug, medical supply, and biologic companies, and requires reporting information related to payments and other transfers of value to physicians and hospitals for values of \$10 or more (or \$100 aggregate in a calendar year). The statutory language is limited to applicable manufacturers of covered devices, drugs, biologics, and medical supplies, for which “payment is available” from certain designated federal healthcare programs and does not include by its terms indirect payments or funding. The information reported will be publicly available through an Internet website in a searchable format.

Section 6002 contains a preemption provision that impacts previously enacted physician payment reporting requirements for drug and device manufacturers in the District of Columbia, Maine, Massachusetts, Minnesota, Vermont, and West Virginia. The federal preemption is not absolute, however, as it applies only to the extent the state laws require reporting of the same information. The preemption does not apply to (1) state laws or regulations that require reporting of different information; (2) reporting by entities other than manufacturers, physicians, or hospitals; or (3) reporting to a federal or state agency “for public health surveillance, investigation, or other public health purposes or health oversight purposes.” Healthcare entities subject to Section 6002 requirements need to anticipate managing transparency requirements at the federal and state levels.

Transparency requirements in the Healthcare Reform Law are not limited to applicable manufacturers under Section 6002. Other sections of the legislation impose other transparency requirements on other health industry sectors. Section 6001, for example, addresses hospital and physician disclosures related to conflicts of interests and hospital disclosures concerning physician availability. Section 6101 imposes immediate requirements on nursing homes to track significant financial information for eventual disclosure once regulations are developed. The required disclosures for nursing homes will relate to ownership and control relationships relating to a facility's governing body, officers, directors, lease arrangements, and entities and individuals that exercise operational, financial, and management control over the facility. This provision will affect investors and investment interests in long-term care facilities. Section 6003 contains physician disclosure requirements, effective January 1, 2010 by its terms, that require physician practices to advise patients who may receive ancillary services from their physician that such services may be obtained from a person other than the in-office provider.

A summary of Section 6002 and of the transparency requirements for nursing homes, physicians, and pharmacy benefit managers contained in the legislation is available [here](#).¹ The full text of House Bill 3590 (Public Law 111-148) can be found at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf.

The Morgan Lewis FDA and Healthcare Practice has been directly involved in representing device and drug companies in government-mandated transparency disclosure requirements as well as counseling healthcare corporations and institutions on compliance with various state reporting requirements. We will continue to monitor the development of government transparency requirements.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the author of this LawFlash, **Kathleen McDermott** (202.739.5458; kmcdermott@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

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1. The chart can be accessed at <http://www.morganlewis.com/pubs/Sec6002TransparencyReportsChart.pdf>.

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