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Physician Payment Sunshine Spreads the Light from Vermont and Massachusetts to All Fifty States

By Joshua J. Freemire

Gifts between pharmaceutical and device manufacturers and prescribing physicians and hospitals have been the focus of regulatory scrutiny for some time now, and recently resulted in wholesale bans, coupled with payment reporting requirements, in both Vermont and Massachusetts. Under section 6002 of PPACA, the reporting requirements of the Massachusetts and Vermont laws have become nationally applicable (along with some new requirements). In fact, the new "Physician Payment Sunshine" provisions significantly expand on the Massachusetts and Vermont laws in at least one important way.

The federal provisions apply to all manufacturers of a "covered drug, device, biological, or medical supply which is operating in the United States" or any U.S. territories, possessions or commonwealths. Importantly, however, *manufacturer* is defined to include both the actual manufacturing entity, which is engaged in "production, preparation, propagation, compounding or conversion of a covered drug, device, biological or supply" and "*any entity under common ownership with such entity* which provides assistance to such entity with respect to the production, preparation, propagation, compounding, conversion, *marketing, promotion, sale, or distribution*" of a covered drug, device, biological or supply. If a non-manufacturing parent company, for instance, provides marketing support to a manufacturing subsidiary, that parent company may be considered a *manufacturer* under the new law. This represents a significant expansion of the laws now in effect in Vermont and Massachusetts. Unlike the Vermont and Massachusetts law, however, the PPACA provisions only require reporting—they do not ban any transfers to physicians or hospitals.

The Physician Payment Sunshine provisions, unlike many in PPACA, are not self-implementing. They will require regulations issued by CMS. PPACA, however, has provided CMS with a fairly detailed skeleton to flesh out.

Under the statutory language, covered manufacturers are required to make annual reports, beginning in March 2013, which detail all payments or transfers of value to physicians or teaching hospitals that occurred during the previous calendar year. *Transfers of value* are defined generally to include a "transfer of anything of value" but specifically exclude:

- Transfers made indirectly, through a third party, where the manufacturer is unaware of the identity of the recipient
- Transfers worth less than $10 up to an aggregate annual limit of $100 per recipient (if this aggregate limit is exceeded, all gifts, including those under $10, must be reported)
- Product samples that are intended for patient use
- Educational materials that "directly benefit patients" or are intended for patient use
- The loan of a covered device, for evaluation purposes, for a trial period not to exceed 90 days
- Items or services provided under a contractual warranty, where the warranty terms are set forth in the purchase agreement
- Transfers to a physician where the physician is a patient and not acting in a professional capacity
- Discounts, including rebates
- In-kind items used for the provision of charity care
- Dividends or other profit distributions from an ownership or investment interest in a publicly traded security
- Payments for the provision of employee healthcare under a self-insurance plan
- Payments for non-medical services, where the recipient is also a licensed professional in a non-medical field

(such as an attorney)
- In the case of a physician, payments for the physician's "services with respect to a civil or criminal action of administrative proceeding" (such as expert witness fees)

For each transfer, manufacturers must report:

- The recipient's name
- The recipient's address, and, where applicable, National Provider Identifier (NPI)
- The amount transferred
- The dates of the transfer(s)
- A description of the form (cash, stock, in-kind items, etc.)
- A description of the nature of the payment (consulting fee, gift, honoraria, etc.)
- If the payment is related to marketing, education or research specific to a particular drug or product, the name of that drug or product
- Any other categories of information CMS deems appropriate

In addition to the above report, manufacturers must also report any ownership or investment interest in the manufacturer held by a physician (or a physician's immediate family member). For each such interest, manufacturers must provide:

- The dollar amount invested
- The value and terms of each investment or interest
- For each payment made to a physician, or to an individual at the physician's direction, much of the same information required for transfers of value
- Any other information identified by CMS

Both of the above reports are to be made electronically, via means to be identified by CMS in regulations to be published no later than October 1, 2011. The information will be tracked by CMS and also made available on a public, searchable website. CMS is required under the statutory language to consult with "affected industry, consumers, consumer advocates, and other interested parties" with respect to its procedures and the design of the public access portal.

Transfers of value made in connection with clinical trials, "new applications" of existing products, or product development for new products will not necessarily be made publicly available. The statute provides that publication of these payments may be delayed for four years, or until the subject product is approved, whichever is sooner. The statute, however, does not define *new applications* or *product development agreements*. CMS, presumably, as part of its new reporting procedures, will further define these terms and provide means for manufacturers to identify such private and sensitive information.

Manufacturers who fail to submit required information are subject to civil penalties from $1,000 to $10,000 per failure, with an annual limit of $150,000. A "knowing" failure to report, however, carries penalties of $10,000 to $100,000 per failure, with an annual limit of $1,000,000. These penalties will be "imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A…" (the Civil Money Penalty statute found at 42 U.S.C § 1320a-7a). Similarly, the statute defines *knowingly* to encompass the definition provided by 31 U.S.C. § 3729(b) (the Civil False Claims Act).

Finally, the national Physician Payment Sunshine provisions specifically provide for preemption of all duplicative state reporting requirements, beginning on January 1, 2012 (one year prior to the end of the reporting period to be reported in March 2013). It does not appear to preempt, however, state bans on gifts or other transfers. Nor does it prohibit states from requiring the reporting of additional or different information than that required under PPACA. The extent of the statute's preemption, then, will remain unknown until such time as CMS promulgates procedural regulations fully identifying all categories of reportable data.

Ober|Kaler's Comments: A national reporting program is the natural result of increased scrutiny with respect to manufacturer/provider relationships. While the new law will create greater work for manufacturers, given that under the new law's low exception limits, manufacturers will essentially need to track all transfers to physicians in all states, the preemption of similar state statutes will streamline such reporting. Of course, manufacturers should read the statute's exceptions closely, and be certain to include them in any new reporting procedures. Further, when proposed,

CMS's regulations will require close review to ensure that reporting procedures remain simple and do not risk exposure of sensitive product development plans.

An Avenue to Disclose and Request that CMS Compromise Stark Liabilities

By Julie E. Kass and Kristin Cilento Carter

Filling the void left by the OIG when it announced last year that it would no longer accept self-disclosures for pure Physician Self-Referral (Stark) Law liabilities, section 6409 of PPACA instructs CMS to develop and implement a self-referral disclosure protocol (SRDP) whereby providers and suppliers can report actual or potential violations of the Stark Law. CMS has six months to develop the SRDP in coordination with the OIG. Once developed, CMS must post SRDP instructions on CMS's website. CMS must designate the person, official or office to which disclosures should be made and provide guidance regarding the effect of the SRDP on corporate integrity agreements and corporate compliance programs.

Significantly, section 6409 expressly authorizes CMS to compromise payment and penalty amounts due and owing for violations of the Stark Law. This change is important because it has previously been unclear whether CMS believed it had the statutory authority to reduce or compromise amounts owed under the Stark Law. In determining whether to reduce amounts owed, CMS is instructed to consider the nature and extent of the improper or illegal practice, the timeliness of a disclosure, the provider's cooperation in supplementing information, as needed, and any other factors CMS deems appropriate.

Ober|Kaler's Comments: The implementation of a self-disclosure protocol for Stark Law liabilities hopefully will provide an effective avenue for providers and suppliers to efficiently disclose actual and potential Stark violations, which sometimes stem from such minor technicalities as an agreement missing a single signature, but which can lead to huge financial liability.

Without more guidance from CMS, however, it is unclear how the newly established protocol will interplay with the OIG Self-Disclosure Protocol in matters involving potential or actual liability under both the Stark law and antikickback statute. Moreover, the law lacks any explicit requirement that CMS involve other agencies, such as the Department of Justice or the OIG, in settling cases under the SRDP.

Lastly, section 6409 does not address the interaction with a separate PPACA provision that requires identified overpayments to be refunded within 60 days. (*See "New 60-Day Time Limits for Reporting and Returning Overpayments" by Joshua Freemire.)* Hopefully, the SRDP will create a mechanism for tolling of the time for any repayment under the filing of a self-disclosure under the SDRP.

While the SRDP has not yet been developed, we have learned that CMS is currently accepting disclosures. It will not be clear, however, how CMS will handle the disclosures or compromise the amounts until the SRDP has been issued. While we do not know if CMS will adopt the same or similar protocols to the OIG, providers desiring to submit a self-disclosure prior to the issuance of the SRDP can look to the OIG self-disclosure protocols as a frame of reference. Providers should stay tuned for more detailed instructions, which, by law, must appear on the CMS's website by late September 2010.

Health Reform Implications for Long Term Care Staffing

By Susan A.Turner

PPACA imposes several new recordkeeping and reporting requirements on long term care facilities related to direct care staffing. Under section 6103 of PPACA, Congress has directed HHS to revise the current Medicare Nursing Home Compare website to ensure that consumers of long term care services can easily access readily understandable information about facility staffing that has been updated by HHS on a timely basis. The new law requires that all the staffing information currently posted on the Nursing Home Compare website continue to be available (such as staff hours per resident day broken out by nursing licensure categories), but also requires HHS to

gather and post information on direct care staffing turnover and staff tenure. Moreover, PPACA requires HHS to include a new piece of information — an explanation of "the relationship between nursing staffing levels and quality of care" — on the Nursing Home Compare website. The legislation does not give any insight into what Congress believes this relationship may be.

The staffing information that will be posted on the Nursing Home Compare website will now be required to be submitted by long term care facilities "in a uniform format" based on "payroll and other verifiable and auditable data" related to staff providing services in the Medicare and/or Medicaid certified portions of the building. Currently, long term care facilities are required to complete CMS Forms 671 and 672 at the time of a standard survey, and the information requested in these forms looks back only to the two-week period prior to that survey. Section 6106 requires HHS to develop an electronic report over the next two years that, in addition to the information currently captured by CMS Forms 671 and 672 and currently posted on the Nursing Home Compare website, will capture information on employee turnover and tenure. Importantly, section 6106 requires HHS to capture direct-care staffing information on agency and contract staff, in addition to facility employees. While Congress did not direct this information to be collected within a particular time frame, the law does require HHS to develop a "regular reporting schedule" for it.

Finally, PPACA creates new accounting and reporting obligations for long term care facilities related to direct care staff. By March 2011, CMS is required to modify the SNF cost report to permit separate reporting of expenses incurred for wages and benefits of direct care staff and separately break out the expenses for various categories of caregivers, such as RNs, LPN/LVNs, CNAs, and other medical and therapy staff. For cost reporting periods beginning on or after March 2012, facilities will be required to separately report direct care expenses using the modified cost report form. Congress has directed that HHS analyze the data separately identified on the new modified cost reports, in conjunction with MedPAC, the OIG, and any other party that HHS deems appropriate, to determine, on an annual basis, SNF spending on direct care services, on indirect care services (such as housekeeping and dietary), capital assets and administrative services. HHS is specifically directed to establish procedures to make this information related to annual expenditures available to interested parties upon request.

Ober|Kaler's Comments: While many states already impose minimum nurse staffing requirements on long term care facilities, either as a condition of licensure or Medicaid payment, the federal Medicare program has largely permitted SNFs to make their own determinations as to how many nurses, at what licensure and training levels, are "sufficient" to meet the needs of their own particular patient mix. Under PPACA, Congress has made clear that it expects HHS to monitor nursing facility direct care staffing much more closely than it has in the past, and also to analyze each facility's direct care staffing in terms of the effect that staffing level may have on the quality of services furnished to the particular acuity mix of that facility. In advance of the new cost reporting and Nursing Home Compare data collection obligations, facilities are advised to review their data collection processes to ensure that they are capable of tracking and segregating hands-on patient care hours worked by both employees and contract/agency staff; patient census data on a daily basis, as well as by patient acuity (RUGs scores); and the costs and expenses related to providing care. Getting a handle on this data now will help facilities comply with the law as each reporting requirement becomes effective over the next 12 to 30 months. Equally, if not more importantly, this data can be used by a facility to set staffing schedules that promote sufficient and cost-efficient staffing, as well as to defend against survey citations of inadequate staffing, and private and/or governmental claims of resident harm as a result of insufficient staffing.