

CMS ISSUES PROPOSED RULE TO IMPLEMENT PHYSICIAN PAYMENT "SUNSHINE" PROVISIONS

EXECUTIVE SUMMARY

On December 14, 2011, the Centers for Medicare and Medicaid Services ("CMS") released a long-awaited proposed rule, Transparency Reports and Reporting of Physician Ownership of Investment Interests ("Proposed Rule"), discussing the implementation of the physician payment "sunshine" provisions of the Patient Protection and Affordable Care Act ("PPACA"), commonly referred to as the "Sunshine Act." See PPACA § 6002, 42 U.S.C. 1320a-7h. The Proposed Rule promotes transparency of financial relationships between certain health care providers (e.g., physicians and teaching hospitals) and manufacturers of drugs, devices, biologicals or medical supplies, as well as group purchasing organizations ("GPOs") through an electronic report to be submitted annually and certified by the Chief Executive Officer, Chief Financial Officer or Chief Compliance Officer of the reporting entity. Under the Proposed Rule, CMS requires applicable manufacturers of drugs, devices, biologicals or medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to submit an annual report describing certain payments or other transfers of value to physicians and teaching hospitals. The Proposed Rule also requires applicable manufacturers and GPOs to report certain information regarding the ownership or investment interests held by physicians or the immediate family members of physicians in such entities. The Proposed Rule can be found at: <http://www.gpo.gov/fdsys/pkg/FR-2011-12-19/pdf/2011-32244.pdf>.

CMS invites comments on the Proposed Rule, which must be received by CMS no later than 5 p.m. on February 17, 2012. Commenters should refer to file code CMS-5060-P and should submit comments in accordance with the instructions described in the Proposed Rule.

SUNSHINE PROVISIONS

Delay of Implementation

Under the Sunshine Act, data collection and reporting was scheduled to commence on January 1, 2012, with the first annual report to be submitted to CMS by March 31, 2013. Under the Proposed Rule, CMS suggests that entities are not required to comply with the reporting requirements until at least 90 days after the Final Rule is issued to allow for a preparation period. The Proposed Rule notes that requiring collection of data for part of 2012 to be reported by March 31, 2013 is still under consideration.

Transparency Reports

Under the Proposed Rule, two types of reports must be submitted to CMS: (1) payments or transfers of value from applicable manufacturers to covered recipients; and (2) physician ownership and investment interests in applicable manufacturers and applicable GPOs.

With respect to the first transparency report, while the Proposed Rule does not further define "transfer of value," it does define "covered recipients" as a physician, other than a physician who is an employee of an applicable manufacturer or a teaching hospital. The Proposed Rule further specifies that the term "physician" includes doctors of medicine and osteopathy, dentists, podiatrists, optometrists and licensed chiropractors, and the term "teaching hospital" includes any institution that receives payments for Medicare graduate medical education reimbursement. The transparency report, a template of which is also suggested in the Proposed Rule, will require applicable manufacturers to disclose payments or transfers of value, regardless of whether the covered recipient specifically requested the payment or other transfer of value, as well as to identify the covered recipient and the form and nature of the payment. Of note, the Proposed Rule excludes 13 types of payments and other transfers of value from the reporting requirements, including, but not limited to: (i) transfers of value less than \$10, unless the aggregate amount transferred to, requested by or designated on behalf of the covered recipient exceeds \$100 in a calendar year; (ii) product samples, discounts; (iii) the loan of a covered device for a short-term trial period; or (iv) any items that meet the definition of charity care. Additionally, the Proposed Rule allows for delayed publication of payments made pursuant to product research or clinical investigations so as to maintain the confidentiality for proprietary information relating to the development of new drugs, devices, biologicals or medical supplies. Covered recipients will be required to review this report prior to submission to CMS as there will be no review period prior to CMS making such information public. CMS believes such report will maximize transparency about the details of the payment or other transfer of value by allowing end users to discern whether the covered recipient actually received the payment and, if not, where it went.



The second type of proposed report requires manufacturers and applicable GPOs to submit an annual electronic report detailing the ownership and investment interests held by physicians or their immediate family members. For purposes of this report, the Proposed Rule uses the terms "physician" and "immediate family member" as they are defined in the Sunshine Act. Thus, for purposes of this report, physician ownership and investments interests include any physician, regardless of whether the physician is an employee of the applicable manufacturer or applicable GPO as well as any ownership and investment interest of any immediate family member. The Proposed Rule further defines "ownership or investment interest" as one that may be direct or indirect and through debt, equity or other means, which includes, but is not limited to, stock, stock options, loans or partnership shares. Specifically excluded from the definition of "ownership or investment interest" is ownership or investment interest in a publically traded security or mutual fund. The Proposed Rule also proposes a template transparency report to be used to submit such data electronically on an annual basis. While the first proposed transparency report does not provide for a review period, CMS provides a 45-day review period prior to the data being made available to the public as an opportunity to correct errors or contest the data submitted by applicable manufacturers and applicable GPOs to CMS. For the sake of clarity, CMS states that manufacturers will be required to submit one report covering payments or transfers of value and another report covering physician ownership and investment interests; however, if an ownership interest is reported under the first transparency report, a manufacturer should not duplicate such disclosure in the second transparency report.

Penalties

The penalties set forth under the Proposed Rule are analogous to those enumerated under the Sunshine Act. Specifically, violators of the reporting requirements will be subject to civil monetary penalties ("CMPs"), capped at \$150,000 annually for failing to report and \$1,000,000 for knowingly failing to report. The Proposed Rule sets forth factors that will be used in determining the amount of CMPs.

CONCLUSION

The Proposed Rule creates a mandatory annual reporting obligation by applicable manufacturers and applicable GPOs. Covered recipients should be aware of such reporting requirements and ensure that data prepared by the applicable manufacturers relating to payments or transfers of value are reviewed prior to submission to CMS. Additionally, as manufacturer and GPO relationships continue to receive heightened scrutiny from federal and state enforcement authorities, physicians and teaching hospitals should review the reporting requirements set forth in the Proposed Rule and provide feedback to CMS in an effort to create practical reporting requirements in the Final Rule.

If you have any questions, would like additional information about this topic or need help preparing and submitting comments, please contact Jeffrey Short at 317.977.1413   or jshort@hallrender.com, Jennifer Viegas at 317.977.1485   or jviegas@hallrender.com or your regular Hall Render attorney.