Final Rule: Transparency Reports and Reporting of Physician Ownership or Investment Interests

Description: This final rule will require applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid or the Children's Health Insurance Program (CHIP) to report annually to the Secretary certain payments or transfers of value provided to physicians or teaching hospitals ("covered recipients"). In addition, applicable manufacturers and applicable group purchasing organizations (GPOs) are required to report annually certain physician ownership or investment interests. The Secretary is required to publish applicable manufacturers' and applicable GPOs' submitted payment and ownership information on a public website.

Major Provisions

Transparency Reports

This rule finalizes requirements for applicable manufacturers to annually report certain payments or other transfers of value to covered recipients. The rule provides definitions of numerous terms, such as applicable manufacturer, and covered drug, device, biological, and medical supply. In addition, the rule also clarifies how applicable manufacturers should report and characterize payments or other transfers of value, including rules for research payments, and indirect payments provided to a covered recipient through a third party. The rule also finalizes which payments or other transfers of value are excluded from the reporting requirements.

In addition, the rule finalizes the requirements for applicable manufacturers and applicable GPOs to annually report information about certain ownership or investment interests held by physicians and the immediate family members of physicians in such entities, as well as payments and other transfers of value to such physicians.

Report Submission, Correction, and Publication

The rule finalizes the processes and requirements for applicable manufacturers and applicable GPOs to submit their reports to CMS, including the specific data elements required to be included in the report format. The rule also details the processes for the review, dispute, and correction period when applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors are provided the opportunity to review, dispute, and propose corrections to reported payments or other transfers of value, or ownership or investment interests, attributed to them.

- Reports required under this subpart must be electronically submitted to CMS by March 31, 2014, and by the 90th day of each subsequent calendar year.
- Organizations and physicians will be able to review and correct the data before it's published on a public website by Sept. 30, 2014.