

Small Entity Compliance Guide

Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests

Federal Register Vol. 78, No. 27, Page 9458, February 8, 2013
42 CFR Parts 402 and 403

CMS-5060-F **RIN 0938-AR33**

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA, Pub.L. 104-121, as amended by Pub. L. 110-28, May 25, 2007) contains requirements for issuance of “small entity compliance guides.” Guides are to explain what actions affected entities must take to comply with agency rules. Such guides must be prepared when agencies issue final rules for which agencies were required to prepare a Final Regulatory Flexibility Analysis under the Regulatory Flexibility Act.

The complete text of this rule can be found on the CMS website at:

<http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Affordable-Care-Act-Section-6002-Final-Rule.pdf> .

This final rule requires 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.

We have created a website (<http://go.cms.gov/openpayments>) to assist the applicable manufacturers and applicable GPOs in understanding the program, including all compliance requirements. This includes requirements for data collection, submission, attestation and corrections. The program requires applicable manufacturers and applicable GPOs to [collect the data for submission to CMS](#). All applicable manufacturers and applicable GPOs, who have information to report, must [register](#) with the Open Payments system using a CMS secure website prior to the submission of data for each reporting year.

Under the Open Payments system, during each program year applicable manufacturers and applicable GPOs are required to [submit data](#) regarding payments or other transfers of value made to covered recipients, plus physician ownership and investment interests. Late data submissions may be considered failures to report and could result in penalties. Registered physicians and teaching hospitals have the ability to [review and dispute](#) data submitted about them before public release. Applicable manufacturers and applicable GPOs can see disputes and correct data before

CMS makes it public. All applicable manufacturers and applicable GPOs should work with physicians, teaching hospitals and physician owners/investors to correct the information.

Additional information regarding requirements for this program can be found at:

<http://go.cms.gov/openpayments>. In addition, there is a helpdesk to help answer any questions openpayments@cms.hhs.gov.