

Physician Payment Sunshine

Current Law

No provision.

Chairman's Mark

The Chairman's Mark would amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and applicable manufacturers with respect to payments and other transfers of value and physician ownership or investment interests in manufacturers. It calls for annual transparency reports, penalties for noncompliance, procedures for the submission of information and public availability of this information.

The Chairman's Mark would require any manufacturer of a covered drug, device, biological, or medical supply that makes a payment or another transfer of value to a physician, a physician medical practice, a physician group practice, or a hospital with an approved medical residency training program to report annually, in electronic form, specified information on such transactions to the Secretary of HHS. The report would include the transfer recipient's name, business address, amount of the payment, date of the payment, a description of the form of the payment, a description of the nature of the payment, if the payment is related to marketing, education, or research specific to a covered drug, device, biological or medical supply the name of that product, and any other category of information that the Secretary determines appropriate. If the recipient requests a transfer of payment to another entity or individual at the request of the recipient the manufacturer should disclose that information. Delayed reporting requirements would apply for payments made pursuant to a product development agreement or clinical trial. Some information would be excluded from these reporting requirements, including payments or transfers of \$10 or less, unless the aggregate annual payments or transfers to a recipient exceeds \$100, in which case all payments or transfers shall be reported, samples intended for patient use, patient educational materials, loan of a covered device for a short-term time period, discounts and rebates, payments made to a physician for the provision of health care to employees, payments to a physician who is also a licensed, non-medical professional if the payment is solely related to non-medical services, payments to a physician solely for services related to a civil or criminal action or an administrative proceeding, and in-kind items used for charity care. This reporting requirement would begin on March 31, 2012 and continue on the 90th day of each subsequent calendar year.

The Chairman's Mark also requires any such manufacturer, or related group purchasing organization to report annually to the Secretary, in electronic form, certain information regarding any ownership or investment interest (other than in a publicly traded security and mutual fund) held by a physician (or an immediate family member) in the manufacturer or group purchasing organization during the preceding year.

Manufacturers or group purchasing organizations would be subject to a civil money penalty (CMP) of not less than \$1,000 but not more than \$10,000 for each payment or transfer not reported. The total amount of the penalties for any annual submission shall not exceed \$150,000. Any manufacturer or group purchasing organization that knowingly fails to submit information would be subject to a CMP of not less than \$10,000 but not more than \$100,000 for each payment or transfer not reported. The total amount of the penalties for this failure to report category of submissions shall not exceed \$1,000,000 annually.

The Chairman's Mark would require the Secretary to establish procedures no later than October 1, 2010 to ensure public availability of this information. Beginning September 30, 2012 and on June 30 of subsequent years, submitted information should be available on an Internet website that meets formatting, search, and usability requirements. In addition to the transfer information, the website should include information on enforcement actions during the preceding year, background information on industry-physician relationships, a separate listing for payments related to clinical research, and other information that the Secretary deems appropriate. The Secretary should also allow recipients an opportunity to submit corrections to their information. This reporting procedure should be established after consulting the Office of the Inspector General (HHS OIG), affected industry, consumers and other parties in order to ensure that the information is presented in an appropriate context. The Secretary would be required to submit an annual report to Congress and the states beginning April 1, 2012.

Effective January 1, 2011 the Chairman's Mark would preempt any state (or political subdivision of a state) law or regulation that requires manufacturers to disclose the type of information required under this provision regarding payments or transfers to covered recipients. The Mark would not preempt any state (or political subdivision of a state) law or regulation that requires the disclosure or reporting of (1) any information not required under this provision; (2) the types of information excluded from reporting requirements under this provision, with the exception of the \$10 de minimis/\$100 aggregate reporting requirement; (3) information by any person or entity other than an applicable manufacturer or covered recipient described above; and (4) information reported to a Federal, state, or local government for public health purposes.

The Secretary would be required to consult with the HHS OIG on the implementation of this section.