ACP American College of Physicians
INTERNAL MEDICINE | *Doctors for Adults*

Brief Summary of the National Physician Payment Transparency Program: Open Payments "Physician Payment Sunshine Act"

(Prepared by the Department of Health Policy and Regulatory Affairs, February 26, 2013)

TOPIC	FINAL RULE SUMMARY	COMPARISON TO ACP COMMENTS SUBMITTED TO THE PROPOSED RULE[1]
General Summary	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 ("referred to as covered recipients"). • Applicable manufacturers and applicable group purchasing organizations (GPOs) 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.	ACP supported the concept of making relationships that the health care industry has with physicians and teaching hospitals more transparent, and the overall intent of this rule to reduce the adverse effects of instances of conflict of interest within health care
Purpose	The purposes of this Act are to: • Facilitate transparency into the financial relationships between industry and physicians and teaching hospitals. • Help reduce the potential for conflicts of interest that physicians or teaching hospitals could face as a result of their relationships with	

[1] ACP's comments submitted to the proposed rule is available at http://www.acponline.org/advocacy/where_we_stand/other_issues/sunshine_provisions_aca.pdf

	manufacturers. • Empower informed decision-making for consumers of healthcare	
Origin of Regulation	This final rule implements the requirements in section 6002 of the Affordable Care Act (ACA) and the provisions were modeled on the recommendations of the Medicare Payment Advisory Commission (MedPAC) and the Institute of Medicine (IOM).	
Who is Responsible to Report Required Information?	The applicable manufactures and GPOs.* In general, • An applicable manufacturer is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or under common ownership with such an entity. • An applicable GPO purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for resale or the distribution of other which is operating in the United States, or in a territory, commonwealth or possession of the United States * Includes only manufacturers and GPOs of drug, device, biological or medical supply in which payment is available under Medicare, Medicaid or CHIP and which, requires a prescription to be dispensed (in the case of a drug or biological) or premarket approval by or notification to the FDA (in the case of a device or a medical supply that is a device). Thus, Over-the Counter (OTC) drug manufacturers are excluded.	The College supported the finalized definition of applicable manufacturer.
Who is a covered recipient?	Physicians defined as including doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors, who are legally authorized to practice by the State in which they practice. The definition applies regardless of whether the physician is enrolled in Medicare and as long as the physician has a current license to practice. The rule does not include as a covered recipient: • medical residents • non-physician providers such as nurse practitioners • a bona-fide employee of the applicable manufacturer Teaching Hospitals defined as any institution that received Graduate Medical	

	Education (GME) or Indirect Medical Education (IME) payments during the most recent year for which such information is available. CMS will publish a list of teaching hospitals annually. Note that Teaching Hospitals are exempt from the ownership and investment provisions of the Act.	
Categories Payment to be Reported	The following forms of payment are required to be reported by the applicable manufacturer: • Cash or a cash equivalent. • In-kind items or services. • Stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment. • Any other form of payment or other transfer of value.* These payments must then be placed into one of the following categories describing the nature of the activity paid for: • Consulting fees. • Compensation for services other than consulting. • Honoraria. • Gift. • Entertainment. • Food and Beverage ** • Travel (including the specified destinations). • Education. • Research.*** • Charitable contribution. • Royalty or license. • Current or prospective ownership of investment interest. • Direct compensation for serving as faculty or as a speaker for a medical education program. • Grant. • Any other nature of the payment or other transfer of value. * An applicable manufacturer or GPO must report payments or transfers of value that are refused by the covered recipient, but directed by the covered recipient to a specific entity or individual.	The College requested increased clarification of payment reporting categories. While CMS has continued to keep the categories broad and flexible, they have added increased definitional clarification and the ability for applicable manufacturers and GPOs to voluntarily provide "context" information regarding the payments/transfers. CMS did directly respond to a request regarding payment for speakers at continuing education events, and has developed two categories reflecting accredited/certified and non-accredited/certified events. CMS agreed with the College's comment to limit the research category to bona fide research activities. CMS did not agree with the College's comment to separate direct and indirect research payment categories. CMS

	** The per-person value of a meal is calculated based on covered recipients that actually partake in the food or beverages provided. *** Note that the Act allows for delays in publication of payments/transfer of value for designated research related to the development of a new product or application to protect confidential, proprietary activities.	finalized that applicable manufacturers must report each research payment once as a single interaction. They must report the name of the individual or entity (regardless of whether it is a covered recipient) that received the payment for the research services, as well as the principal investigator(s). CMS believes that the recipient of the payment could include individual principal investigators, teaching hospitals, nonteaching hospitals or clinics.

Information Required to be Submitted by Applicable Manufacturer and GPO	There are three similar but different reporting information requirement lists dependent of whether the report concerns (1) payment or transfer of value from applicable manufacture to covered recipient, (2) payment or transfer of value from applicable manufacture to covered recipient specifically related to research, and (3) physician ownership or investment interests in an applicable manufacturer or GPO. Categories on all or select lists include:
	
	• Applicable manufacturer or GPO's name;
	• Covered Recipient's
	  o Name (as listed in the National Plan & Provider Enumeration System (NPPES)) including middle initial
	  o Specialty (physician only);
	  o Primary business street address (practice location)
	  o National Provider Identifier (NPI) #;
	  o State Professional License Number(s)
	• Amount of payment or other transfer of value
	• Date of payment or other transfer of value
	• Form of payment or other transfer of value:
	  o Cash or cash equivalent	

	○ In-kind items or services ○ Stock, stock option, or any other ownership interest ○ Dividend, profit or other return on investment • Nature of payment Activity • The name of the related drug, device, biological or supply ○ National Drug Code (NDC) of related covered drug/biological, if any ○ For devices/med supply ▪ Name under which its marketed; or ▪ Therapeutic area or product category ○ "Non-covered" product ○ "None" • Eligibility for delayed publication (<u>research payments</u>) • Name of entity that received the payment or other transfer of value, if not provided to the covered recipient directly (indirect payments) ○ Payment to 3rd party <u>at request of</u>; or ○ <u>Designated on behalf of</u> covered recipient • Dollar amount invested by each physician or immediate family member of the physician • Value and terms of each ownership or investment interest • Payments or transfers of value to physician owners or investors (or immediate family member) • Statement providing additional context for the payment or other transfer of value (optional)	
Activities Excluded from Reporting	Activities excluded from reporting <u>include</u>: • Payments or other transfers of value less than $10, except when the total annual value of payments or other transfers of value provided to a covered recipient exceeds $100.	ACP commented that speaker payments subsidized by an applicable manufacturer or GPO should be reported whether directly or indirectly received.

	• Small incidental items (e.g. pens or notepads) that are under $10 that are provided at large scale conferences and similar large scale events are excluded from aggregate tracking and reporting. • Educational materials that directly benefit patients or are intended for patient use. * • Payments or other transfers of value provided to a third party (e.g. physician professional organization) that are distributed to a covered recipient but the applicable manufacturer or GPO does not "require, instruct, direct or otherwise cause" the third party to provide the payment to a covered recipient. • Payments or other transfers of value provided as compensation to a speaker of an accredited or certified continuing education provider event supported by an applicable manufacturer ** • Attendees at an accredited or certified continuing education event whose fees have been subsidized through the CME organization by an applicable manufacturer *** • Buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a large-scale conference or similar event conference or similar large-scale event • Discounts, including rebates • In-Kind items for the provision of charity care • Product samples • Short term loan of covered device (no more than 90 days) • Value received by a covered recipient acting as a patient • A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund • Value received related to a civil or criminal action or administrative proceeding • Indirect payments or other transfers of value where applicable manufacturer is unaware of the identity of the covered recipient * The exclusion does not include educational materials (e.g. textbooks, journal reprints) provided to covered recipients for their own education and that do not	CMS finalized that speakers at accredited/certified continuing events that meet specified requirements are excluded from reporting. This position was taken given the inherent protections from undue influence already enacted by these accredited /certified continuing education providers. CMS responded positively to the College's request that attendees at accredited/certified continuing education events be excluded from reporting. CMS agreed that provided educational material must directly benefit the patient to be excluded and added helpful clarification to this distinction in the final rule. CMS provided requested clarification regarding the issue of indirect payments/transfers and under what conditions reporting is included or excluded.

	"directly" benefit patients. ** Exclusion only applies if: • Accreditation or certification of the continuing education provider comes from the AACME, AAFP, ADA, AMA or AOA. • The applicable manufacturer does not pay the speaker directly (payment goes through the educational provider) and • The applicable manufacturer does not selected the covered recipient speaker and provide the third-party provider with a distinct set of speakers to be considered. ***Any travel or meals provided by an applicable manufacturer to specified covered recipients associated with these events must be reported under the appropriate nature of payment categories.	
Important Dates for Reporting	For 2013 --- applicable manufacturers and GPOs must begin tracking information on August 1, 2013 and must report all required information electronically to CMS by March 31, 2014 with attestation that the information reported is timely, accurate, and complete to the best their knowledge and belief. For subsequent years --- applicable manufacturers and GPOs must report all required information with attestation electronically by the 90th day of the subsequent calendar year	The College supported the finalized delay in reporting to ensure that physicians have adequate notice of the final transparency rule and to provide CMS and manufacturers/GPOs an adequate opportunity to establish a reporting process that is consistent with the statute and congressional intent.
Review and Correction Period	CMS has finalized a 45-day review and correction period, during which covered recipients and physician owners and investors may register and then sign into a secure website and review the data submitted by applicable manufacturers and applicable GPOs on their behalf and choose to dispute certain payments or other transfers of value, or ownership of investment interests. Information from the current and previous completed reporting year will be available for review. CMS each year, using email list serves, online postings (including both on the CMS website and the Federal Register) and directly (likely by email) will provide to any physicians or teaching hospitals that have registered with CMS	CMS responded positively to the College's concern regarding an adequate review period by adding an additional 15 day period for disputed reports to be resolved. In addition, covered recipients will have up to a two-year period to review and correct reported data. ACP also recommended that

	ahead of time information regarding the review and correct period. CMS will also work with physician professional societies, applicable manufacturers and GPOs to voluntarily assist in disseminating this information.	applicable manufacturers and GPOs should be required to share information that they will report on some regular basis to covered recipients prior to the actual reporting deadline date. In the finale rule, CMS has decided to allow applicable manufacturers and GPOs to voluntary report data to covered recipients on an on-going basis, but not require it.
Dispute Resolution and Reporting	Applicable manufacturers and GPOs may begin resolving the dispute and correcting the data at any time during the 45 review and correction period. Following the end of the review and correction period, applicable manufacturers and GPOs will have an additional 15 days to correct data for purposes of resolving disputes, and after which they may submit (and provide attestation for) updated data to CMS to finalize their data submission. Undisputed data will be finalized for publication after the close of the annual 45-day review and correction period. The resolution of the dispute is the responsibility of the applicable manufacturer or GPO, and the covered recipient or physician owner or investor. The review process will allow covered recipients and physician owners and investors to electronically flag information in dispute and provide necessary additional information including a proposed solution. The system will notify the appropriate applicable manufacturer or GPO of the dispute, detailing the information submitted by the disputing covered recipient or physician owner or investor. The applicable manufacturer or GPO will be responsible for submitting corrected data and re-attesting to the new data by the end of the 15-day resolution period. Payments or other transfers of value or ownership or investment interests that cannot be resolved by the end of the15-day resolution period will be marked as	

	"disputed," but the applicable manufacturer's or GPO's most recent attested data subject to the dispute will be the only account of the information published. All parties will have the opportunity to review and amend the data during the subsequent review and annual correction period. CMS plans to monitor the rate of disputes and resolutions, including whether an applicable manufacturer or applicable GPO has an abnormally high number of disputes or has an abnormally high rate of unresolved disputes.	
Public Reporting Dates	Information collected in 2013 will be released on the public website on September 30, 2014. In future years, the public reporting date will be on June 30th of the subsequent year.	
Public Website	The final rule provides only broad and general information regarding the public website in order to allow flexibility over the details of the website and allow the opportunity to work with stakeholders on its development. The goal is to provide a website that is user-friendly and provides accurate and understandable information to the public. The website will clearly state that disclosure of a payment or other transfer of value on the website does not indicate that the payment was legitimate nor does it necessarily indicate a conflict of interest or any wrong doing. The site will also contain access to FAQs and other methods to help users find and understand this information. Based on statute, the website will not contain the physician NPI, it will allow for searches across multiple fields and be downloadable.	The College supported and CMS finalized the inclusion of language on the website reflecting that a reported payment/transfer "does not indicate that the payment was legitimate nor does it necessarily indicate a conflict of interest or any wrongdoing." CMS did not agree with ACP's comment to also include links to relevant ethical/professionalism materials available from various physician organizations, including the College.
Penalties	Only applicable manufacturers and GPOs are vulnerable to the prescribed civil monetary penalties (CMPs). CMPs of not less than $1,000, but not more than $10,000, will be assessed for each payment or other transfer of value or ownership or investment interest not reported. The total amount of civil money penalties will not exceed $150,000.	

	Failing to submit payment information will result in a CMP of not less than $10,000, but not more than $100,000, knowingly for each payment. The penalty will not exceed $1,000,000. Total penalties may not exceed $1,150,000.	
Pre-exemption of State Law	The Act preempts any State or local laws requiring reporting, in any format, of the same type of information concerning payments or other transfers of value made by applicable manufacturers to covered recipients. State and local entities may require reporting of information for payments or other transfers of value reported to CMS, which are not required under Federal law.	
Relationship to Anti-Kickback and False Claims Act	Compliance with this Act does not exempt applicable manufacturers, GPOs, covered recipients, or physician owners/investors (or their immediate family) from potential liability under the Federal Anti-kickback, False Claims Act or similar legislation.	
Annual Reports	CMS is required to submit annual reports regarding the program annually to Congress and the States.	
Impact Analysis regarding Covered Recipients	CMS finalized the estimate that this data review on average would take 1 hour for individual physicians and 5 hours for their supporting staff annually. It further estimated that only 50 percent of physicians would have a reportable interaction with industry. CMS estimated that all teaching hospitals would have at least some reportable events. They have increased from the proposed rule the impact assumptions for teaching hospitals to require a compliance officer on average 40 hours annually to review the submitted data and an estimated 80 hours annually of administrative support staff for each teaching hospital to help maintain their records.	ACP commented that impact estimates were underestimates. CMS agreed that the impact on teaching hospitals was underestimated in the proposed rule and was increased. CMS did not agree that the physician estimates were undervalued.
Additional Information	CMS "Physician Payment Sunshine Rule" website at http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html	

	CMS fact sheet on "Physician Payment Sunshine Rule" at http://www.cms.gov/apps/media/press/factsheet.asp?Counter=4522 CMS presentation on "Physician Payment Sunshine Rule" at http://policymed.typepad.com/files/cms-sunsine-presentation-feb-19-2013.pdf The Physician Payment Sunshine Rule" from the Federal Register at https://www.federalregister.gov/articles/2013/02/08/2013-02572/medicare-medicaid-childrens-health-insurance-programs-transparency-reports-and-reporting-of#h-24	