

Urology Payments from Industry in the Sunshine Act

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Abstract

Introduction: Payments to practitioners from drug and device manufacturers or group purchasing organizations are reported in the Centers for Medicare and Medicaid Services (CMS) databases as a part of the Sunshine Act. Characterizing these payments is a necessary step in identifying conflicts of interest and the influence of payments on practice patterns, if any. Payments have never been analyzed in detail among urologists.

Methods: We reviewed the most recent CMS Open Payments database for the full year 2014, released on June 30, 2015. Urology practitioners were extracted and the database was analyzed for number of total payments, total dollar value of payments, mean, median and number of physicians, number of manufacturers, and number of drugs/biologicals. Data were further categorized according to provider specialty, form of payment, nature of payment, practitioner ownership and dispute status.

Results: Payments totaled \$32,450,382. Practitioner payments were unevenly distributed, with a median payment of \$15. The majority of payments were in the form of food and beverage. Female pelvic medicine practitioners received the highest payments out of the provider specialties. The largest categorical difference from the median was in the form of stock, options and other ownership interests (\$24,050). Ownership status and disputed payments were associated with payment values above median values (\$400 and \$61, respectively).

Conclusions: There are major disparities in industry payments to urology practitioners. Whether this influences practice patterns remains to be seen, although identifying categorical differences in payments is an important first step in the process.

Key Words: Patient Protection and Affordable Care Act, industry, compensation and redress, conflict of interest, disclosure

Financial ties between health care providers and manufacturers of pharmaceuticals and medical devices have long been scrutinized and are a matter of public interest.¹ On March 23, 2010 Congress signed into law Section 6002 as part of HR3590, better known as the Sunshine Act of the Patient Protection and Affordable Care Act. Its intent was to

speak to public concerns over physician and industry relationships, clarify financial relationships, consolidate a location for reporting and monitoring, and stop dishonest research, education and clinical decision making.² Although it is common practice to disclose conflicts of interest in educational lectures, the Sunshine Act dramatically expands

Submitted for publication November 16, 2015.

No direct or indirect commercial incentive associated with publishing this article.

The corresponding author certifies that, when applicable, a statement(s) has been included in the manuscript documenting institutional review board, ethics committee or ethical review board study approval; principles of Helsinki Declaration were followed in lieu of formal ethics committee approval;

institutional animal care and use committee approval; all human subjects provided written informed consent with guarantees of confidentiality; IRB approved protocol number; animal approved project number.

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the criteria and accessibility to this information. On February 8, 2013 the final rulings were decided and the first full year of disclosures for 2014 was published on June 30, 2015.^{3,4}

To our knowledge, payments from manufacturers and group purchasing organizations to physicians have never been described among urologists. Whether payments influence practice patterns is an ongoing topic of investigation.⁵⁻⁷ Quantifying the magnitude and nature of such payments is an important first step in establishing the absence or presence of conflicts of interest.

In this study we identified the characteristics of payments in the Sunshine Act database. Special attention was paid to categories where payments were disproportionately distributed. Analysis at this level will enable investigators to better focus study of influence on practice patterns in the future.

Materials and Methods

Data and Study Population

We used the CMS Open Payments files to identify all payments to health care providers from covered manufacturers and group purchasing organizations. A covered manufacturer produces products that are eligible for payment by Medicare, Medicaid, or the Children's Health Insurance Program, and are under the jurisdiction of the U.S. Food and Drug Administration. The 3 databases available were Research, Ownership and General Payments. The Research database involves research related payments, Ownership measures the magnitude of ownership stakes and the General Payments database consists of all other payment types. Urologists were identified from the 2014 General Payments database by filtering by physician specialty. Listed urologist specialties were urology (categorized here as general urology), female pelvic medicine and pediatric urology. Ownership stakes are contained in the Ownership database, although payments in a given year with equity/investment interests are included in the General Payments database as a form of compensation.

Teaching hospitals were excluded from the study because data on individual beneficiaries are not listed in this categorization. However, individual providers who are employed by teaching hospitals are included in the analysis. We excluded 2,579 recipients who were nurses and 15 recipients who were Doctors of Dentistry and Doctors of Optometry. Six payments were valued at \$0.00 (all to 1 physician) and were excluded. Our final cohort included 235,239 payments among 9,343 recipients.

Payment Characteristics

Recipient data were recorded, including recipient ID, first name, middle name, last name, suffix, address, state and ZIP code. Provider data were recorded, including physician type, physician specialty and license state. Manufacturer information included ID, name, state, name of drug or biological and ID of drug or biological. Payment information included payment amount, date, number of payments, form of payment, nature of payment, physician ownership indicator, dispute status indicator, and third-party recipient identifiers if applicable. Payment characteristics were stratified for analysis across provider specialty, form of payment, nature of payment, ownership indicator and dispute status.

Statistical Analysis

We summarized payment characteristics in the CMS database. Parametric variables are presented as means and SD. Nonparametric variables are presented as medians and IQR. We examined the characteristics of payments and the top 10 payments to urology practitioners. The distribution of payments was analyzed according to cumulative percent. Lastly, we generated box plots of payments stratified according to provider specialty, form of payment and ownership indicator. Due to the significant skew of the data a log₁₀ transformation was performed on payments before graphing box plots to enable visual clarity. We did not perform descriptive statistics because categories of payments are not independent variables and there was a large number of observations. Therefore, the data are presented without p values. Sensitivity analysis was performed on total payments, means and medians by performing 2-tailed exclusions at the 1% and 5% levels. All analyses were performed using SPSS® version 22. This study used a public database and was institutional review board exempt.

Results

Between January 1, 2014 and December 31, 2014 a total of 235,239 nonresearch and nonteaching hospital payments were present in the database across 9,343 recipients (average 25 payments per recipient). The total payments were \$32,450,382, ranging from a minimum payment of less than \$1 to a maximum payment of \$472,946 (table 1). Sensitivity analysis demonstrated a reduction in total payments to \$16,391,101 and \$5,932,316 at 1% and 5% exclusion, respectively. Mean payments were reduced from \$138 to \$71 and \$28, respectively. Overall median payments did not change. Payment characteristics were stratified across provider specialty, form of payment, nature of payment,

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