

Conflicts of Interest and the CMS Open Payment Registry

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Agenda

- Introductions
- General policies
 - Conflicts of interest
 - CMS Open Payment Registry
- CMS Open Payment Registry review checklist
- Open Payment Dashboard Demo
- Questions

Shannon Sumner CHC, CPA Principal ssumner@pyapc.com Shannon manages PYA's Regulatory Compliance Services and serves as the Firm's Compliance Officer. A CPA certified in healthcare compliance, she has more than two decades' experience in healthcare internal auditing and compliance programs. She advises large health systems and legal counsel in strengthening their compliance programs, and aids in areas of Anti-Kickback Statute and Stark Law compliance. Shannon also assists health systems regarding compliance with Corporate Integrity Agreements (CIAs) and Non-Prosecution Agreements (NPAs), conducts health system merger/acquisition/divestiture due diligence activities, and advises health system governing boards on their roles and responsibilities for effective compliance oversight. At the direction of the Department of Justice, Shannon has served as the healthcare compliance and internal audit subject-matter expert for the largest federal compliance co-monitorship of a health system in U.S. history.



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Introductions

Introductions



Jason Hardin CPA Director jhardin@pyapc.com Jason leads PYA's Business Intelligence & Analytics service line and has been with the firm for more than 10 years. A certified public accountant, Jason leverages his strong foundation in accounting and finance to translate data into custom business intelligence solutions for clients. Jason has extensive experience in healthcare claims analytics, financial modeling/analysis, and dashboard development. Jason implements analytics to provide litigation support on a variety of complex cases.



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General Policies: Conflict of Interest



- Does the organization have a Conflict of Interest (COI) policy and procedure?
 - Is there a code of conduct which outlines permitted/not permitted activities?
- Is the COI policy applicable to all employees and physicians, including medical staff?
- Does the COI policy address relationships with vendors, including:
 - ✓ Consulting arrangements
 - ✓ Honorarium
 - ✓ Travel
 - ✓ Meals
 - ✓ Entertainment
- Is there a person/department responsible for auditing COIs?
- Is there a vendor relationship policy for physician practices, and has this policy been communicated to such vendors?

General Policies: CMS Open Payment Registry



- Does the organization have a procedure for reviewing the CMS Open Payment Registry and does it include the following?
 - Frequency of review (upon hire, upon contract initiation, upon credentialing, etc.)
 - ✓ Dollar threshold for review (e.g., \$5,000; \$10,000; etc.)
 - ✓ Research and resolution of any reportable events
 - ✓ Analysis of potential conflicts, such as serving in a decisionmaking capacity related to the drug or device manufacturer
 - Monitoring of OIG/DOJ enforcement activities related to drug or device manufacturers and relationships with current employees/contractors/medical staff
 - ✓ Reporting of analysis to management and governance



CMS Open Payment Registry Review



- Have the COI forms been reviewed and compared to the CMS Open Payment Registry?
- Are there reportable events under the policy?
- Are any physicians in a decision-making capacity, whereby they may influence purchasing decisions for pharmaceuticals or medical devices? This includes medical directors, product selection committee, drug formulary committee, etc.



CMS Open Payment Registry Review



- Is the proportion of time spent speaking, traveling, etc., appropriate?
 - Full-time employees?
 - Part-time employees?
- Are these activities provided for in existing employment agreements?
- Should any of the consulting fees/honoraria have been paid to the health system?
 - Is there a written contractual agreement between the physician and the vendor?
 - Is this agreement kept on file?
 - Are the fees reasonable?

CMS Open Payment Registry Review



 Has an inventory of physician relationships with vendors (per the Open Payment Registry) been compared with the vendor listing to determine if any physicians, either on medical staff or employed, have existing arrangements with vendors utilized by the health system?



Speaker Programs

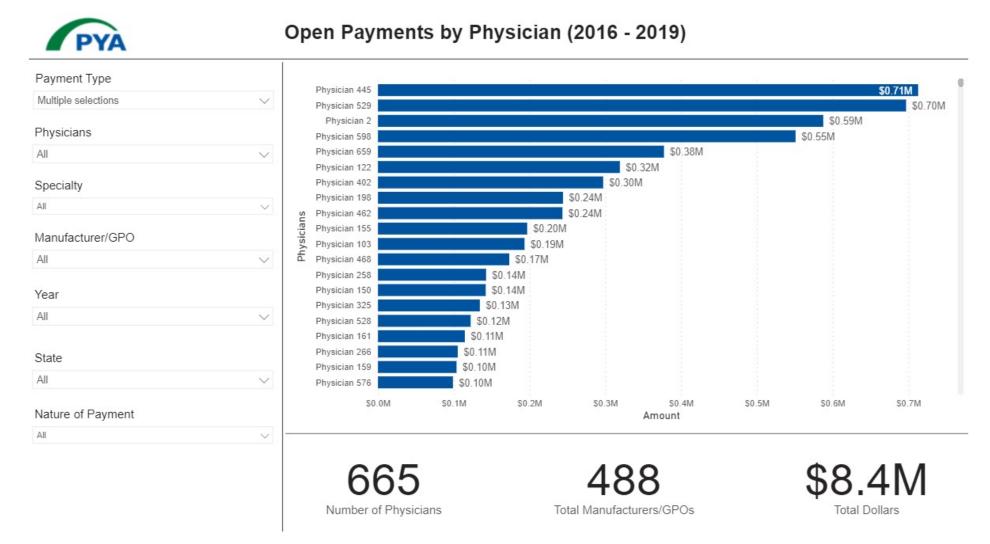




- Is the information available through other means that do not involve remuneration (e.g., various online resources, medical journals)?
- Is the event held in a location that is not conducive to learning (e.g., entertainment or sports venue)?
- Has there been little to no new developments related to the pharmaceutical or medical device?
- Is the provider a repeat speaker program attendee for the same product or device?
- How was the provider selected to attend the speaker program (e.g., high prescriber, ordering physician for device)?
- Has the organization assessed whether the remuneration is above Fair Market Value?
- Is the information relevant to the selected audience?

CMS Open Payment Dashboard Demo







Questions?



Thank you!



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