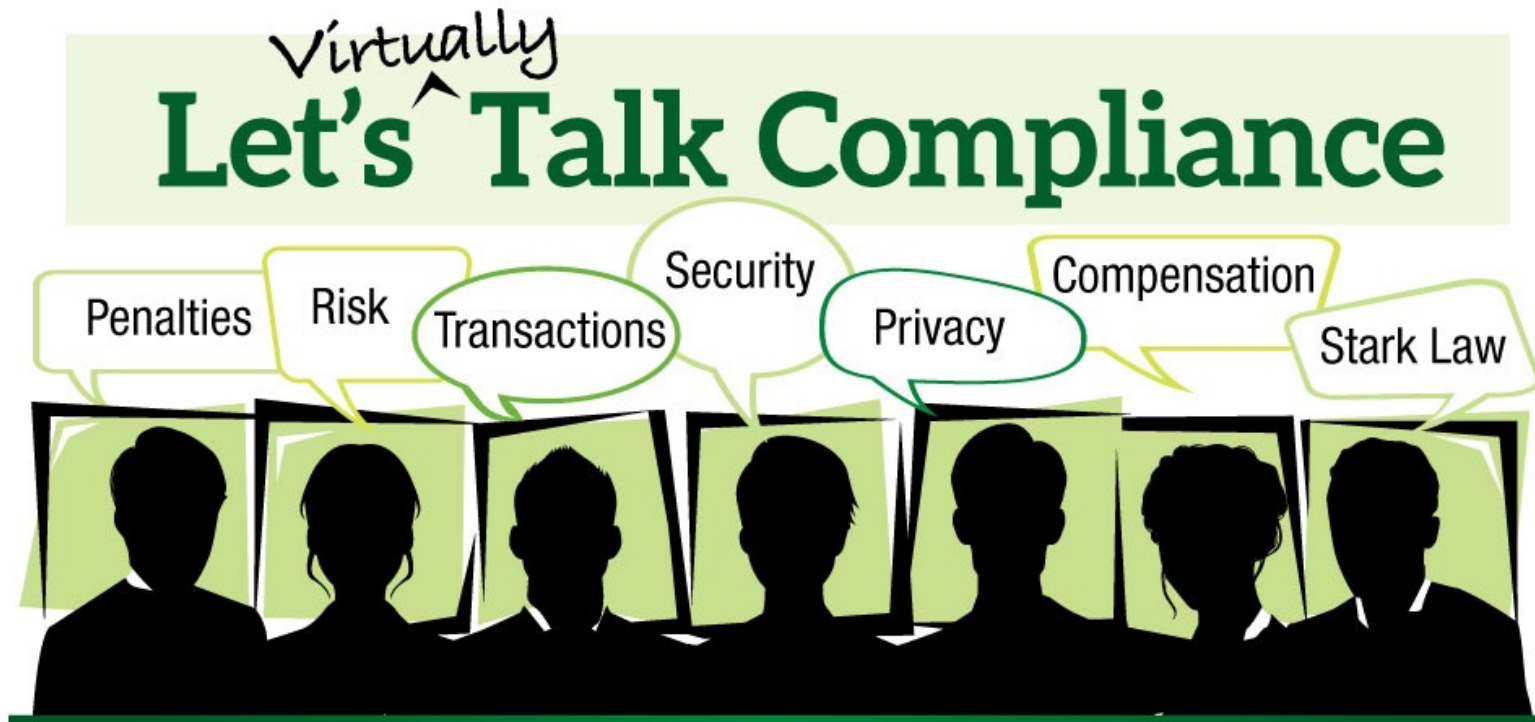


# Let's Talk Compliance

One-Day Compliance Master Class



A group of professionals in a meeting around a table with documents and coffee. The image is a background for a presentation slide. It shows a man in a suit and a woman with glasses looking at documents on a table. There are coffee cups and a teapot on the table. The text is overlaid on the right side of the image.

**SESSION #2**

# Compliance Considerations Related to Provider Compensation

*Angie Caldwell, Carol Carden, Kyle Faget, and Judy Waltz*

January 19, 2022

# Agenda

## Background and Compliance Best Practices for:

- Key Opinion Leader Compensation
- Open Payments Program
- Ancillary Payment Sources
- Telemedicine Compensation
- Value-Based Exceptions
- APP Supervision Compensation



# Key Opinion Leader Compensation – Background and Compliance Best Practices

## Background

- Physician consultants are an important resource to device and medical product manufacturers
- Physicians provide training, speaking, advisory services, customer site visits, etc.

## Best Practices

- Creating compensation consistency through a tiered approach
  - Tiers based on clinical experience, educational training, leadership experience, publication history, and presentation experience, among others
- Consistent and thoughtful use of KOL premium



# Open Payments Program – Background

- Requires drug, device, biological, or medical supply manufacturers or vendors, distributors or wholesalers to disclose to CMS any payments of value made to physicians or teaching hospitals
- Certain manufacturers and GPOs are required to disclose physician ownership or investment interests held in those companies.
- These organizations are required to disclose payments or transfers of value (items or information) made to a covered recipient
- The threshold for individual payments in 2022 is \$11.64, and the total annual payment threshold is \$116.35
- CMPs for failure to report are \$1,000 to \$10,000 for each payment, transfer of value, ownership, or investment not timely or accurately reported



# Open Payments Program – Compliance Best Practices

- Know what is being paid by vendors to your employed physicians
- Ensure code of conduct and conflict of interest policies and procedures outline what activities with vendors and companies are permitted and not permitted
- Medical staff should be trained and educated on the importance of ethical and appropriate vendor interactions
- Engage vendors by requiring they attest to conflict of interest policies and open payments reporting
- Annually review the CMS Open Payments database. Identify providers in a position of influence over purchasing and contracting decisions.
- Consider creation of a conflicts of interest committee to identify, monitor, and resolve conflicts
- Consider compliance work plan audits to assess compliance with conflicts and disclosure practices





# Ancillary Payment Sources

Additional Considerations



# Payments from Independent Laboratories

- **OIG Special Fraud Alerts: Laboratory Payments to Physicians (6/25/2014)**
  - Alert identifies several characteristics of blood-specimen, collection, processing and packaging arrangements that may be kickbacks
    - Payment exceeds FMV for services actually rendered by the party receiving the reimbursement;
    - Payment also covered by a third party, e.g., Medicare;
    - Remuneration directly to HCP, rather than HCP's practice;
    - Payment on per-specimen basis for more than one specimen collected during a single patient encounter (volume-based);
    - Remuneration conditioned on type of tests (ie, more expensive);
    - Payment to HCP when lab placed a phlebotomist in the physician's office.
  - Carve outs for federal health care payers do not get around the concern.



# Payments from Product Manufacturers

- OIG Special Fraud Alerts: Speaker Programs (11/16/2020)
  - List of suspect characteristics of problematic speaker programs: (cont.)
    - Lots of programs offered on same topic/same market;
    - No new FDA info prompting program];
    - Repeat attendees;
    - No legit reason to attend (e.g., friends & family);
    - Sales/marketing business units influence the selection of speakers or the company selects HCP speakers or attendees based on past or expected revenue that the speakers or attendees have or will generate by prescribing or ordering the product(s);
    - Payment > FMV or takes into account v/v of past business generated or potential future business.

# Payment for Advertising: Physician Services

AMA Code of Medical Ethics - Opinion 9.6.1

*Advertising & Publicity:* Nothing in this opinion is intended to discourage or to limit advertising and representations which are not false or deceptive within the meaning of Section 5 of the Federal Trade Commission Act. At the same time, however, physicians are advised that certain types of communications have a significant potential for deception and should therefore receive special attention. For example, **testimonials of patients** as to the physician's skill or the quality of the physician's professional services tend to be deceptive when they do not reflect the results that patients with conditions comparable to the testimoniant's condition generally receive.



# Payments for Product Sales: DTC Advertising

AMA Code of Medical Ethics – Op. 9.6.7(h)

*Direct-to-Consumer Advertisement of Prescription Drugs:* Whenever possible, assist authorities to enforce existing law by reporting advertisements that do not:

1. Provide a fair and balanced discussion of the use of the drug product for the disease, disorder, or condition.
2. Clearly explain warnings, precautions, and potential adverse reactions associated with the drug product.
3. Present summary information in language that can be understood by the consumer.
4. Comply with applicable regulations.
5. Provide collateral materials to educate both physicians and consumers.

# Payments for Product Sales: Health-Related Products

AMA Code of Medical Ethics – Op. 9.6.4 *Sale of Health-Related Products*:  
Physicians who choose to sell health-related products from their offices or through their office website or other online venues have ethical obligations to [most relevant portions only]:

- Offer only products whose claims of benefit are based on peer-reviewed literature or other sources of scientific review of efficacy that are unbiased, sound, systematic, and reliable.
- Address conflict of interest and possible exploitation of patients by:
- Fully disclosing the nature of their financial interest in the sale of the product(s), either in person or through written notification, and informing patients of the availability of the product or other equivalent products elsewhere.
- Avoid exclusive distributorship arrangements that make the products available only through physician offices.



## Payments for Product Sales: Non-Health Related Goods

AMA Code of Medical Ethics, Op. 9.6.5 *Sale of Non-Health Related Goods*: The sale of non-health-related goods by physicians presents a conflict of interest and threatens to erode the primary obligation of physicians to serve the interests of their patients before their own. Furthermore, this activity risks placing undue pressure on the patient and demeaning the practice of medicine.

# Telemedicine Compensation – Background

- Pandemic spurred exponential growth
- Can be used in all settings – general clinical (i.e., the provider is 100% tele-based), call coverage, and in “downtime” (i.e., telemedicine coverage during hospitalist coverage hour)
- Growth called into question how the related compensation should be valued – is the service rendered different than in person services?
- Payer reimbursement varies widely



# Telemedicine Compensation – Compliance Best Practices

- Document the provider’s responsibilities around telemedicine – when, where, who, how, why
- Document the time commitment (burden and intensity of telemedicine service) and expertise required
- Is any “double-dip” accounted for correctly?
- Document the commercial reasonableness of the arrangement. Does the telemedicine service accomplish a legitimate and realistic business purpose that furthers the healthcare entity’s strategic and financial goals?





# Special Payment Issues Relating to Telehealth

- Identify clearly what it is that the payment is for
  - Physician Relationship
    - Evolving changes to DIY patient care may not yet be reflected in state laws – what does it mean to establish a physician/patient relationship? Responsibility
    - Pain cream cases
    - Medicare requirements in 42 CFR 410.32 that all diagnostic services not ordered by a physician treating the patient will be deemed medically unnecessary (i.e., not covered)
  - Exception for first COVID-19 test
  - State requirements regarding practice of telemedicine
  - Documenting special elements for telehealth claims – e.g., technology used, place of service, time, etc.
  - Credentialing issues
    - Licensing in appropriate state
    - Credentialing/Enrollment for specific providers



# Value-Based Exceptions - Background

- Regulations effective January 21, 2021
- Intent was to encourage the transition of health care from volume to value
- Stark Exceptions
  - Full Financial Risk
  - Meaningful Downside Financial Risk
  - Value-Based Arrangements



# Value-Based Exceptions

- AKS Exceptions (focused on payer arrangements)
  - Full Financial Risk
  - Substantial Downside Financial Risk
  - Care Coordination Arrangements
  - Outcomes-Based Payment Arrangements (within Personal Services and Management Contracts Safe Harbor)
- Is anyone using the exceptions?
- Is it difficult to align the exceptions?
- What will the best practices be?



# APP Supervision Compensation – Background

- Quick expansion of APP utilization at a substantial cost to employers
- Utilization of APP varies (i.e., personally-performed, incident-to, and split shared)
- Insurance payer reimbursement guidelines and government regulation have complicated the determination of who is doing what between the APP and physician
- 2022 MPFS implementation will change productivity attribution for APPs in the inpatient setting



# APP Supervision Compensation – Compliance Best Practices

- Know who is doing what, where, and when
- Physician compensation should be for physician services provided by the physician
- If physicians are paid on a productivity basis, understand how the productivity will be attributed between physician and APP
- If supervision stipends are utilized, compensate reasonably and consistently
- Understand the commercial reasonableness of the physician-APP team



# Thank you.

Angie Caldwell  
Principal  
PYA, P.C.  
813.424.3700  
acaldwell@pyapc.com

Carol Carden  
Managing Principal of  
Valuation Services  
PYA, P.C.  
865.673.0844  
ccarden@pyapc.com

Kyle Faget  
Partner  
Foley & Lardner LLP  
617.502.3292  
kfaget@foley.com

Judy Waltz  
Partner  
Foley & Lardner LLP  
415.438.6412  
jwaltz@foley.com

ATTORNEY ADVERTISEMENT. The contents of this document, current at the date of publication, are for reference purposes only and do not constitute legal advice.

Where previous cases are included, prior results do not guarantee a similar outcome. Images of people may not be Foley personnel.

© 2022 Foley & Lardner LLP

