

THANK YOU FOR JOINING ISMPP U
TODAY!

The program will begin promptly at 11:00 am eastern

ISMPP WOULD LIKE TO THANK.....

the following Corporate Platinum Sponsors for their ongoing support of the society

The logo for Amgen, featuring the word "AMGEN" in a bold, blue, sans-serif font with a registered trademark symbol.The logo for Biocentric Inc, consisting of the word "BIOCENTRIC INC" in a brown, sans-serif font, with a thin brown circle positioned behind the "O" in "CENTRIC".The logo for Caudex Medical, featuring a green infinity symbol above the words "CAUDEX MEDICAL" in a green, sans-serif font.The logo for CHC Group, with "CHC" in a large, grey, sans-serif font, followed by a bar chart icon with three bars of increasing height, and the word "GROUP" in a smaller, grey, sans-serif font below it.The logo for Complete Medical Communications, featuring a blue sphere with the word "COMPLETE" in white, followed by a green horizontal bar containing the words "MEDICAL" and "COMMUNICATIONS" in white.The logo for KnowledgePoint360, featuring a stylized blue and white wave icon to the left of the text "KnowledgePoint360" in a blue, sans-serif font.The logo for MedThink SciCom, featuring a green molecular structure icon above the words "MedThink" and "SciCom" in a green, sans-serif font.The logo for Pfizer, featuring the word "Pfizer" in a white, italicized, sans-serif font inside a blue oval.

REMINDER....

- Next seating of the CMPP exam is September 1-30, 2011
- Application deadline: August 15, 2011
- Why certify?
 - *Recognized as a credible expert in the medical publications arena*
 - *Validation of your skills and knowledge to your employer, colleagues and external partners*
 - *Enhanced value to potential business partners*
 - *Demonstrated leadership and confidence within your professional community*
 - *To keep ahead in a very competitive job market and corporate environment*

Today's program: 1 Recertification Credit Hour

FACULTY

- Presenter

- Katherine Lauer

- Partner, Latham & Watkins LLP

- Moderator

- Kim Pepitone

- Director of Credentialing and Professional Development, ISMPP

- Certified Medical Publication Professional

DISCLOSURE: KATHERINE LAUER

- Partner, Latham & Watkins LLP
- Global Co-chair, Healthcare and Life Sciences Practice Group, Latham & Watkins LLP
- No competing financial interests
- The content and opinions expressed are mine
- Nothing in this presentation should be considered legal advice

DISCLOSURE: KIM PEPITONE

- Employee of ISMPP
- No competing financial interests
- The content and opinions expressed are mine

A CLOSER LOOK: HOW THE PATIENT
PROTECTION & AFFORDABLE CARE ACT
AND STATE LAWS IMPACT INDUSTRY
COLLABORATIONS WITH ACADEMIC
RESEARCHERS

AND

WHAT MIGHT THIS MEAN FOR MEDICAL
PUBLICATION PROFESSIONALS?

August 10, 2011

OBJECTIVES

- To understand the Physician Sunshine Act
 - Definitions
 - Details on reporting
 - Steps to prepare
- To be aware of how this may impact the work we do as medical publication professionals

AS YOU LISTEN TO TODAY'S PRESENTATION, CONSIDER...

- What will you need to do differently?
- What information will you need to track?
- Who are the (new) stakeholders that you will need to work/communicate with?
- How will we communicate this information/answer questions for investigators/authors?
- Most important 'watch words'—**transfer of value**

FEDERAL PHYSICIAN PAYMENT TRANSPARENCY REPORTS

- On 3/31/13, “any applicable manufacturer that provides a payment or other transfer of value to a covered recipient” (or to any individual at the request of a covered recipient), must report certain information to the Dept. of Health and Human Services (DHHS) regarding those payments and other transfers of value, for a reporting period of calendar year 2012

TRANSPARENCY REPORTS: PROCEDURAL NEXT STEPS

- An agency within DHHS will be tasked with administering Sunshine
- Most specifics regarding reporting requirements will remain unknown until rules are promulgated
- Key dates
 - By 10/1/11, DHHS will establish procedures for report submission and define terms
 - By 1/1/12, companies must begin tracking payments and other items of value
 - By 3/31/13, transparency reports must be submitted to DHHS for calendar year 2012
 - By 9/30/13, DHHS will make reports publicly available on the internet

“APPLICABLE MANUFACTURERS”

- “Engaged in the production, preparation, propagation, compounding or conversion” of a “drug, device, biological or medical supply”
 - (OR “under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a drug, device, biological, or medical supply”)
- For which payment is available under Medicare, Medicaid, or a state Children’s Health Insurance Program

“COVERED RECIPIENTS”

- Physicians and hospitals
 - Except physicians who are employees of the manufacturer
- Payments and other transfers of value to an entity or individual at the request of, or designated on behalf of, a covered recipient must be reported under the name of the covered recipient

PAYMENTS AND TRANSFERS OF VALUE

- Generally, anything of value provided to a covered recipient
 - Fees for service/honoraria, food, travel, educational items, research, charitable contributions, grants, royalties or licenses, etc.
- Certain items are excluded from reporting, including
 - Payments under \$10, unless the aggregate amount paid to a covered recipient exceeds \$100 per year
 - Product samples and educational materials for the benefit of patients
 - Loan of a covered device for trial period ≤ 90 days
 - In-kind items provided for use in charity care
 - Items or services provided under a warranty
 - Discounts (including rebates)

DATA TO BE REPORTED

- Covered recipient's name, address, and National Provider Identifier
- Amount, date, and description of the payment or transfer of value
- Product name to which the payment is related
- Any other categories that DHHS deems appropriate

PHYSICIAN OWNERSHIP INTEREST REPORTS

- By 3/31/13, any “applicable manufacturer” or “applicable group purchasing organization” (GPO) must report certain information to DHHS regarding any ownership or investment interest held by a physician (or his/her immediate family member) in the applicable manufacturer or GPO, for a reporting period of calendar year 2012

INTERNET PUBLICATION

- Publicly available information must
 - Be searchable, clear, and understandable
 - Be easily aggregated and downloaded
 - Contain information reported by manufacturers
 - Contain a description of any enforcement actions taken regarding the reporting requirement during the preceding year
 - Contain background information on industry-physician relationships
 - Contain any other information DHHS determines would be helpful to the average consumer
 - List information related to product research agreements and clinical trials separately

PREEMPTION OF STATE LAWS

- Federal reporting requirements will preempt laws that are similar or weaker than this provision
- Will not preempt laws that are more restrictive
 - Lower limits of payments
 - Additional items to be reported
 - Additional recipients (i.e., PAs/NPs)
 - Gift bans

VERMONT'S PRESCRIBED PRODUCTS LAW

- VT requires manufacturers to disclose expenses related to clinical trials at VT locations, including
 - Gross compensation
 - Directly salary support for each HCP
 - Expenses paid on behalf of investigators
- Must be disclosed either (a) after the date of FDA approval of the product or (b) two calendar years after the payment was made, whichever is earlier
- If a manufacturer delays disclosure of payments, it must identify minimum information to the Attorney General's office, including clinical trial name, start date, and link to the national clinical trials registry

MINNESOTA'S REPORTING LAW: PAYMENTS TO PRACTITIONERS

- MN requires manufacturers to disclose
 - All payments, honoraria, and compensation to MN HCPs totaling more than \$100 per year
- Manufacturers are prohibited from giving any “gift of value” to a practitioner
- “Gift” does not include
 - Reasonable honoraria or expenses for an HCP to serve as faculty at a professional or educational conference
 - Compensation in connection with a genuine research project
 - Educational materials and publications

QUESTIONS.....

To ask a question, please type your query into the 'Q&A' chat box at the bottom left of your screen. Every attempt will be made to answer all questions.

QUESTIONS, DAMNED QUESTIONS, AND THE SUNSHINE ACT!

- Payment or other transfer of value
 - Does this apply to indirect payment for medical writing support?
 - How will such value be calculated?
 - How will this be attributed among authors?
 - Including sponsor authors?
- How will fair market value be determined?
 - How will fair market value be reconciled with medical writing fees?
- What may need to be addressed in disclosure statements to journals?

THANK YOU FOR ATTENDING!

We hope you enjoyed today's presentation.

***Next ISMPP U: Wednesday, September 14
Stay tuned for details!***

**Please take a moment to fill out the survey you will receive following today's program.
Your valuable feedback helps develop our future educational offerings.**