

# Physician Sunshine Act

## Impact on Academic Medical Centers

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**UC Irvine Health**

# HHS/CMS Goals with the Physician Sunshine Act

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- Addresses public concerns about physician and industry relationships.
- Makes financial relationships among industry, physicians and teaching hospitals clear and transparent.
- Provides one place for financial interactions to be reported and monitored.
- Makes it easier for physicians and other stakeholder groups to make sure the information reported about them is accurate.
- Minimizes risk of increased healthcare costs.
- Identifies potential inappropriate influence on research, education and clinical decision making.
- Stops conflict of interest that can harm patients and their care .

# Physician Sunshine Act: Summary

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Section 6002 of the Affordable Care Act added section 1128 G to the Social Security Act which requires transparency in payments from pharma and device manufacturers to physicians and academic medical centers (teaching hospitals).

Applicable manufacturers of drugs, devices, biological, or medical supplies covered by Medicare, Medicaid or the Children's Health Insurance Program (CHIP) are required to report annually to the Secretary **certain payments or transfers of value provided to physicians (excluding residents) or teaching hospitals ("covered recipients")**.

In addition, applicable manufacturers and applicable Group Purchasing Organizations (GPOs) are required to report to CMS certain ownership or investment interests held by physicians or their immediate family members annually certain physician ownership or investment interests.

## Summary of Rule

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Manufacturers must begin tracking payments as of August 1, 2013.

Pharmaceutical, device, medical supply companies will be required to notify HHS of any payment to a physician or teaching hospital of \$10.00 or more.

If value is less than \$10, the manufacturer must report if the aggregate amount exceeds \$100 in a calendar year.

Payments will be posted and publicly available on CMS website. Information to be sent to HHS by 3/31/2014 for payments made to physicians and teaching hospitals beginning on 8/1/2013 through 12/31/2013.

Data will be first published by 9/30/2014. Annually in subsequent years by June 30<sup>th</sup>.

## UC Irvine Health perspective

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- The Physician Sunshine Act gives us a tool that, for the first time, permits an independent review of records for individual physicians and medical center procurement.
- Goal: Achieve transparency in the medical center's relationship with vendors and in physicians' interaction with industry.
- We believe this transparency will benefit our patients.
- Act complements existing UC policies, such as UC Vendor Relations Policy to control vendor presence in medical centers.
- Primary challenge: Ensuring that each physician reviews their data prior to the public release.

# Reportable Payments or Transfers

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- Gifts
  - Entertainment
  - Education
  - Charitable contributions
  - Research (bone fide research activities including clinical investigations that are subject to both a written agreement or contract between the applicable manufacturer and the organization conducting the research)
  - Grants
- AMC Only**
- Space rental or facility fees (teaching hospital only)
- Royalty or licenses
  - Consulting fees
  - Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program
  - Honoraria
  - Current or prospective ownership or investment interest
  - Compensation for service as faculty or as a speaker for an accredited or certified continuing education program
  - Food and beverage (when identities known)
  - Travel (including specified destinations) and lodging

## Covered Payments Potentially Impacting the AMC

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- Charitable contributions
- Research (bone fide research activities including clinical investigations that are subject to both a written agreement or contract between the applicable manufacturer and the organization conducting the research)
- Grants
- Gifts
- Entertainment (as well as food and travel)
- Education (including loans of devices >90 days)
- Space rental or facility fees (teaching hospital only)

## Verification of Data

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The applicable manufacturer can give the AMC (and physician) the chance to see the information before sending it to CMS. Process is voluntary.

In 2014, physicians and teaching hospitals will be able to register to verify their data prior to public posting, initiate disputes with the pharma or device company regarding erroneous data, and request correction of erroneous data.

CMS will give physicians and teaching hospitals 45 days to review and work with the applicable manufacturers to correct information after the file has been submitted to CMS. After the 45 days, the manufacturers have 15 days to submit corrections. The review and correction period starts at least 60 days before the information is public.



## Verification, Continued

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- In the review period, the provider or AMC can dispute information that is not correct with the manufacturer (this is at manufacturer's option).
- If data is disputed, CMS will notify the manufacturer that the information is being disputed, but will not mediate the dispute directly.
- Once dispute is resolved, manufacturer must send CMS a revised report for the correct data and re-attest it is correct.
- CMS will update data from the current and previous year at least once annually, in addition to the initial data publication that followed the submission.

## Potential Benefits for Academic Medical Center

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- Helps AMC achieve goal of transparency.
- Adds transparency to AMC purchasing and decision-making process for devices and pharmaceuticals.
- Adds transparency to AMC purchasing and decision-making process for devices and hospital formulary based on recommendations from physicians.
- Research grants: transparency in how much is paid by sponsor for sponsored projects. May provide contract negotiation advantage.
- Level playing field in transparency of relationships.

## Potential Risks for Academic Medical Center

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- Criticism if physicians and AMCs fail to take steps to reconcile possible conflicts of interest and inconsistencies with self-reported data.
- May make charity donations and equipment donations more difficult and more restricted in future.
- Potential for patient and public scrutiny of relationships and additional questions from patients and the public.
- New tools for other groups that rely on voluntary reporting of conflicts of interest by physicians. Risk may be inconsistent with prior reported data or payments. For examples, research disclosures made in past may not match data reported to HHS.

## Mitigating the Risk

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- Develop or strengthen process for medical staff disclosure(s)
- Ensure procurement policies which recognize the potential for conflict of interest at AMC.
- Strategy to deal with conflict if medical staff member's name is published and there has not been full disclosure.

## Challenges

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- Challenge in tracking accuracy of payments, especially in large Academic Medical Center. Example: tracking loans of devices being tested on trial basis which exceed 90 days.
- Narrow time frame for hundreds of physicians and a complex AMC to review and dispute incorrect data.
- Individual physicians are responsible for reviewing and correcting their own data.
- No mandatory requirement that disputed information has to be corrected.

## What providers and AMCs should do

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- Become familiar with the types of information and payments that will be reported.
- Keep records of all payments and other transfers of value received from applicable manufacturers or applicable GPOs.
- Register with CMS and subscribe to the listserv to receive updates about the program.
- Look at the information submitted on you.
- Work with applicable manufacturers and applicable GPOs to make sure the information is correct.

# Appendix

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