

HCCA ANNUAL COMPLIANCE INSTITUTE

# Charity or Fraud?

When Good Deeds Won't Go Unpunished

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# Charitable Factors

- U.S. has largest charitable sector in world
- Many institutional providers are 501(c)(3) exempt nonprofits
  - must provide charity care, community benefit
  - academic institutions conduct medical research
- Drug, device industry is provider-dependent
  - key source of innovation
  - sole source of referrals.

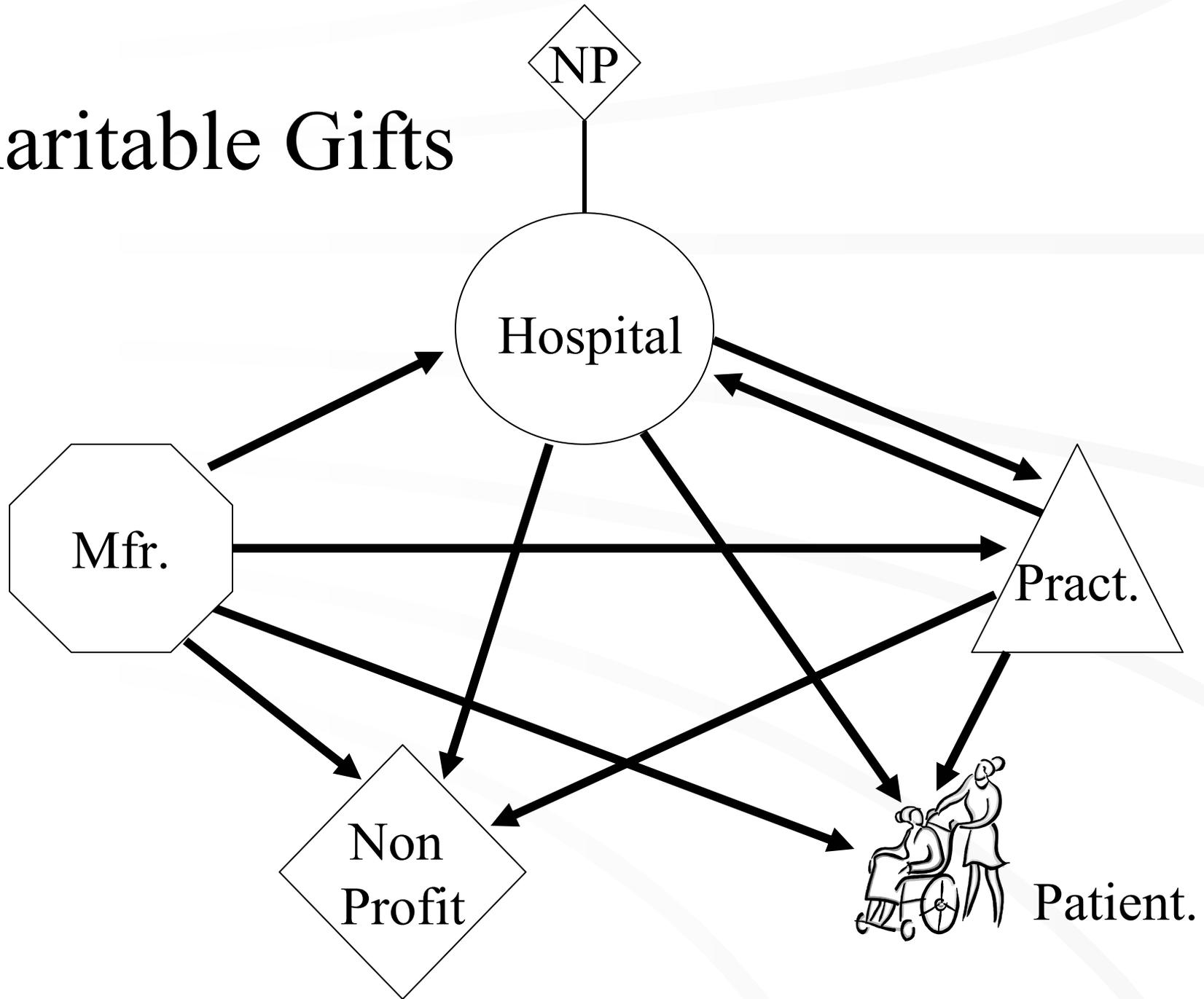
# What do we mean by “charity”?

- Remuneration
- Either to:
  - recipient of health care item/service
  - referral source
- Without FMV exchange, and
- With charitable purpose/pretext.

# Examples:

- Free/discounted services to patients
  - waiver of service fees (including copay)
  - free goods
- Educational grants to providers
- Charitable grants to providers/foundations
- Event sponsorships
- Support of scientific research.

# Charitable Gifts



# Anti-Kickback Act

- 42 U.S.C. §1320a-7b(b). A criminal statute which:
  - prohibits offer, payment, solicitation, receipt
  - of any remuneration
  - for either:
    - referral of patients, or
    - purchase, order, arrangement or recommendation
  - federally reimbursed items/services.

# Anti-Kickback Act

- “Single purpose” rule applies:
  - Greber, 860 F.2d 68 (3rd Cir. 1985)
  - Kats, 871 F.2d 105 (9th Cir. 1989)
  - Bay State Amb., 874 F.2d 20 (1st Cir. 1989)

***Few Safe Harbors Apply  
to Charity!***

# New Stark Exception for Physician Charitable Donations

42 C.F.R. § 411.357(j) (issued Mar. 26, 2004):

- Bona fide charitable donation by a physician to a tax-exempt organization (or to supporting org.)
- Donation must not be solicited or made in manner that takes into account volume/value of referrals
- Donation must not violate anti-kickback statute or other laws.

# Anti-Patient Inducement Act

- 42 U.S.C. §1320a-7a(a)(5). A civil statute which:
  - prohibits payment of remuneration
  - to influence Medicare/Medicaid beneficiary’s selection of a provider/supplier/item
  - federally reimbursed
- Negligence standard applies: “knows or should know”!

# State Fraud & Abuse Law

- 42 states have anti-kickback/”Stark” laws
  - some apply to state payors, others “all-payer”
  - many found in professional licensure statutes (“fee-splitting”)
- IRS/state charitable trust laws
  - prohibition against private benefit/inurement
  - diversion/waste of trust assets.

# OIG Advisory Opinions

<http://oig.hhs.gov/fraud/advisoryopinions/opinions.html>

- ⌘ 97-1, 97-2 and 98-17: dialysis industry subsidies of insurance premiums for financially needy ESRD patients
- ⌘ 98-3, 00-11: donated ambulance, equipment
- ⌘ 98-6, 00-5, 02-16: waiver of copay for gov't sponsored clinical trials
- ⌘ 99-7: waiver of copay in Nat'l Eye Care Project
- ⌘ 00-3: free services by volunteers to hospice patients
- ⌘ 00-7: free transport to chemo, dialysis, radiation patients
- ⌘ 01-2: solicitations for hospital charitable fundraiser
- ⌘ 01-9: hospital financial grants to CHC.

# Advisory Opinions (cont.)

- ⌘ 01-14: waiver of charges and copays for screenings at satellite clinic serving majority uninsured population
- ⌘ 02-1: drug industry-funded charity funding premiums and copays for chronically ill patients using companies' drugs
- ⌘ 02-13☹: pharma-funded charity funding copays for its drugs
- ⌘ 02-14☹: free personal safety equip to hemophila patients
- ⌘ 03-4: free pagers to homebound patients
- ⌘ 04-4: free vision screening tests to infants
- ⌘ 04-15: grants by charity to defray drug therapy costs
- ⌘ 04-18: hospital foundation donations to nonprofit hospice.

# OIG Special Advisory Bulletin

<http://oig.hhs.gov/fraud/fraudalerts.html#2>

- Gifts/inducements to beneficiaries (8/02)
  - “Bright-line” guidance set \$10/\$50 de minimis
  - Inducement doesn’t need to be advertised:
    - “even if a provider does not directly advertise or promote the availability of a benefit to beneficiaries, there may be indirect marketing or promotional efforts or informal channels of information dissemination, such as ‘word of mouth’ . . . .”
  - Independent entities may be used to select beneficiaries (e.g., patient advocacy groups).

# New guides re discounts/waivers

- Thompson letter and CMS Q&A (2/19/04)
  - [www.hhs.gov/news/press/2004pres/20040219.html](http://www.hhs.gov/news/press/2004pres/20040219.html)
- OIG Summary Guidance (2/2/04)
  - [www.oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA021904hospitaldiscounts.pdf](http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA021904hospitaldiscounts.pdf)
- CMS FAQ (12/04)
  - [www.cms.hhs.gov/providers/FAQ\\_Uninsured\\_Additional.pdf](http://www.cms.hhs.gov/providers/FAQ_Uninsured_Additional.pdf)

# Waiving Medicare copays

- A “safe harbor” to the Antikickback *and* Anti-Inducement Acts allows copay waivers for inpatient hospital PPS services if:
  - hospital doesn’t claim as bad debt or otherwise shift burden to other payors
  - waiver is made without regard to reason for admission, length of stay, or DRG
  - waiver is not part of a price reduction agreement between the hospital and a third-party payor. 42 CFR §1001.952(k).

# Waiving Medicare copays

- The 1996 HIPAA included carved-out from the definition of “remuneration” waivers of any Medicare copays that are:
  - not advertised;
  - not routinely offered; and
  - made after determination of individual financial need *or* reasonable collection efforts. 42 USC § 1320a-7a(i)(6)(A).
    - *NOTE*: OIG says Medicaid eligibility does not substitute for individualized determinations of need.

# Waiving Medicare copays

- What constitutes prohibited “advertising” of discounts?
  - Publishing policy vs. trolling for patients
  - Targetting Medicare beneficiaries
  - Attempt to differentiate from competition
  - “White coat” marketing.

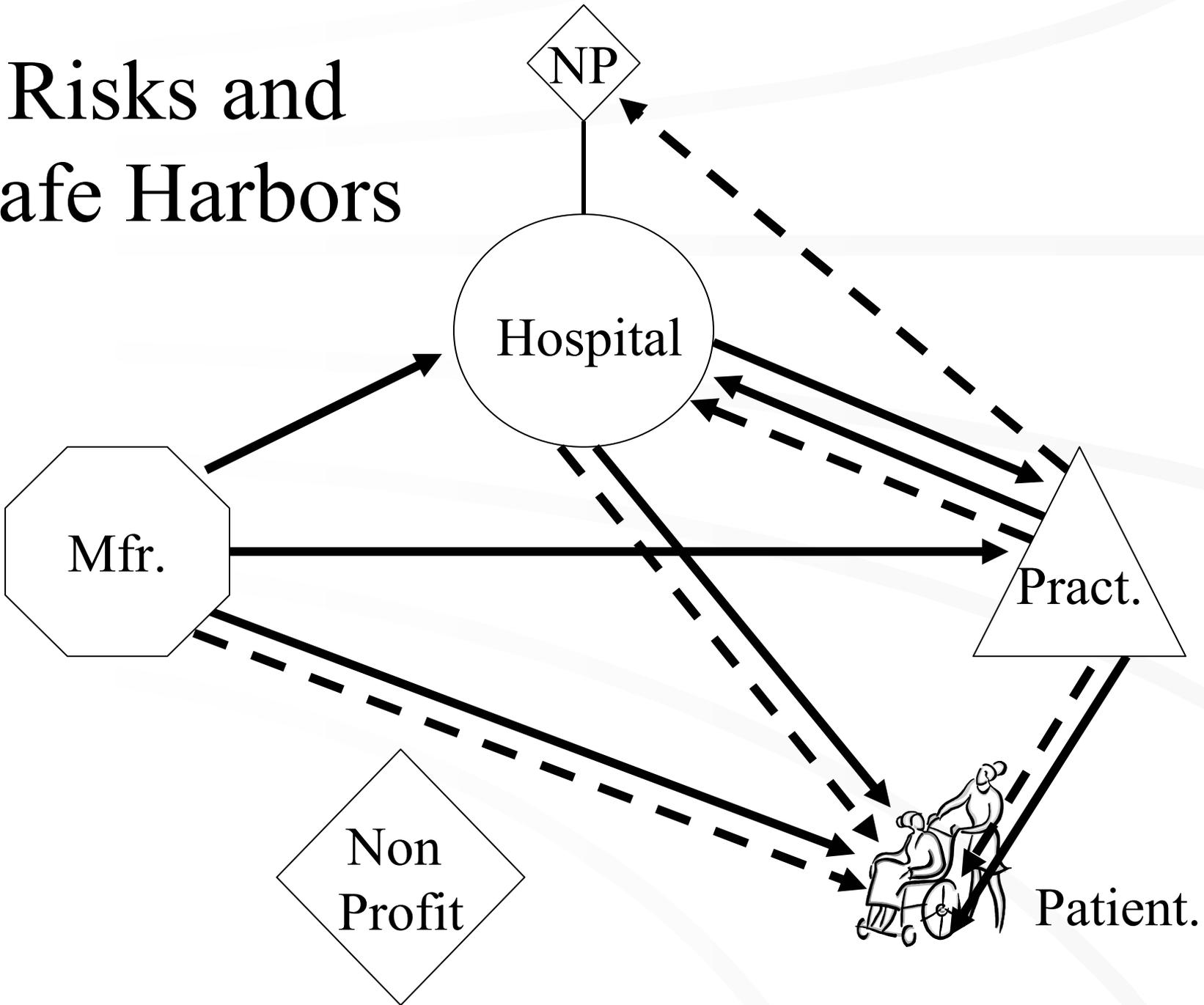
# Determining financial need

- Adopt financial need guidelines with objective criteria
- Apply the guidelines uniformly (i.e. to both Medicare and non-Medicare patients)
- Recheck patient's eligibility at reasonable intervals
- Document determinations of need (e.g., retain forms, questionnaires and/or records of patient interviews).

# Waiver of Copays

- Waiving charges, copays are “ok”
  - categorically, for the totally uninsured
  - with some restrictions, for the underinsured.
- Individual determinations of need are not required for the uninsured
  - waivers do not effect Medicare payments for outliers or new technology.

# Risks and Safe Harbors



# OIG Pharma Compliance Guide

<http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>

- 67 Fed. Reg. 62057 (Oct. 3, 2002)
- Risk areas included:
  - sponsorships of educational conferences
  - scholarships and educational funds
  - research/education grants
- Factors recommended:
  - Is the gift to a person in a position to generate business?

# Compliance Guidance (cont.)

- (cont.) Does the gift take into account the volume/value of potential business?
- Is the gift nominal value/lack FMV?
- Is the gift unrelated to any services at all other than referrals of Federal beneficiaries?

# Industry Codes of Ethics

- PhRMA Code (July '02)
  - [www.phrma.org](http://www.phrma.org)
  - “Arrangements that fail to meet the minimum standards set out in the PhRMA Code are likely to receive increased scrutiny. . . .” OIG Compliance Program Guidance for Pharma.
- AdvaMed Code (Jan. '04)
  - [www.advamed.org](http://www.advamed.org)

# Professional Codes of Ethics

- AMA
  - E-8.061 “Gifts to Physicians from Industry”
    - Gifts should primarily benefit px or relate to physician’s work, not be of “substantial value”
    - “Modest” meals/gifts o.k. if serve “genuine educational function”
    - Conference expenses should not be paid directly to physicians
    - “Reasonable honoraria,” payments for “genuine” consultation services permitted
- Other codes: ABA, HCCA, etc.

# Company's own Code of Conduct

- Avoiding the appearance of improper activity
- “Intend to influence OR can be inferred to influence . . .”

Some scenarios . . .

# Scenario #1

Your nonprofit hospital wants to establish a golf tournament to raise funds for new equipment and medical research. The hospital intends to solicit donations and sponsorships starting at \$4,000 per hole in exchange for event tickets and advertising at the tournament. To be successful, you need significant sponsorship income. Your CEO tells you to solicit your vendors.

# Scenario #2

HaloMed Inc. manufactures a device that controls seizures through electronic stimulus to the brain. A neurologist has proposed to a HaloMed sales manager that HaloMed fund a trip by the neurologist to Africa to provide free SeizeOff implants to needy children suffering from seizure disorders. The neurologist happens to be a significant referral source for SeizeOff. The neurologist has always been active in Third World issues, but he does not work through any established charity. He asks for HaloMed to reimburse his travel expenses, plus provide free product.

# Scenario #3

To hone its image as a cutting-edge orthopedic device company, SpineRod Inc. has decided to play a leadership role in physician orthopedic education. SpineRod's marketing director has three proposals:

First, this year SpineRod would like to pay all travel expenses and conference fees of 20 orthopedic surgeons to attend the Annual Meeting of the Society of Orthopedic Surgeons (“SOS”) in Orlando. SpineRod would select the physicians with input from its sales force.

## Scenario #3 (cont.)

Second, for 2006 and beyond, in order to better administer its educational grants (as well as get a tax deduction), SpineRod would establish a scholarship program through a nonprofit private foundation that SpineRod would create and fund. The board of the new nonprofit, which would be appointed by SpineRod, would select the physician scholarship participants. The scholarships would fund the travel, meals and registration expenses of recipients at the Annual Meeting of SOS in Orlando.

## Scenario #3 (cont.)

Third, sensing your reaction to the previous proposal, the marketing director modifies her proposal as follows: The scholarship recipients would be selected by the Chair (or his/her designee) of the American Board of Orthopedic Surgeons (ABOS) based on criteria ABOS would decide. However, SpineRod would make receipt of the scholarship contingent upon the physician-recipients attending a 2-hour presentation of SpineRod's products held over dinner at a 5-star hotel and restaurant adjacent to the conference, for which SpineRod will pay.

## Scenario #3 (cont.)

Lastly, in order to raise its profile in the world of academia, SpineRod proposes to endow a chair in orthopedic surgery at Johns Hopkins University for a five-year period in the amount of \$500,000. The University's affiliated hospital is a major purchaser of SpineRod devices, and its orthopedic faculty practice includes some of the company's most prominent and respected referral sources.