

HCCA PHILADELPHIA REGIONAL
HEALTHCARE COMPLIANCE
CONFERENCE-2020
TODAY'S COMPLIANCE ISSUES

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TODAY'S COMPLIANCE ISSUES

- WHAT I PROMISED TO DISCUSS (before COVID19)
 - Managing Conflicts of Interest Reporting in Healthcare organizations
 - Compensation issues for physicians and executives-Stark, nonprofit, Internal Revenue Code
 - Pharmaceutical assistance programs-learning from Corporate Integrity Agreements

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TODAY'S COMPLIANCE ISSUES

- COVID19-Impact on Healthcare organizations
- Demands on nurses, physicians, staff, management
- Hospital financial impact of COVID19 patients
- Loss of elective surgery and procedures
- Medically unnecessary days
- What is the role of compliance during pandemic?
- Risk? Reporting? Claim documentation? Hotline management?
- What are prudent risks in compliance?
- When people are stressed and tired, mistakes will happen

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TODAY'S COMPLIANCE ISSUES COVID19 Responses

- State DOH Guidance (health.pa.gov)
 - Hospital guidance (May23,2020 handout)
 - Testing before discharge to nursing facility
 - Facility specific reporting (SNF)
 - SNF immediate jeopardy complaints and facility reports
 - Targeted infection control survey-CDC identified
- CMS prioritization of survey activities (March 23)
- Other guidance: Roadmap for Resuming Elective Surgery (aha.org)

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TODAY'S COMPLIANCE ISSUES- COVID19 Responses

- Fraud Alerts-COVID19 scams (OIG, OAG)
- Protection of front line workers (NY OAG)
- Nursing Home hotlines (NY OAG)
- Pandemic Response Accountability Committee (Pandemic.oversight.gov) oversee \$2.4 trillion in aid to individuals, businesses, support for hospitals and other medical providers, airlines and cruise ships
- COVID-19 Hospital Response(OEI 06-20-00300) HHS OIG report on emergency preparedness and response survey (March 2020)
- Coronavirus.gov
- CDC.gov/coronavirus
- HHS/OIG Application of OIG authorities to COVID19 arrangement

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COVID19 COMPLIANCE

- Compliance in governance issues-what role?
 - Board reporting, education and engagement
 - Filing and reporting (state DOH, federal, charities)
 - Audit/990 involvement (accurate reporting and review, “going concern” qualification to audit, management letters)
 - Risk assessment/revision
 - Mergers, affiliations, dissolutions
 - Management of endowment and institutional funds
 - Payroll and withholding taxes

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”GOING CONCERN”

- If the auditor believes there is substantial doubt about the entity's ability to continue as a going concern for a reasonable period of time, he should (1) obtain information about management's plans that are intended to mitigate the effect of such conditions or events, and (2) assess the likelihood that such plans can be effectively implemented.
- The Audit Committee needs to know

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Identifying Conflicts of Interest

- “Conflict of interest affects virtually every aspect of medicine, including research, teaching, and clinical care.” JAMA editorial 2018
- “a conflict of interest arises whenever activities or relationships compromise the loyalty or independent judgment of an individual who is obligated to serve a party or perform certain roles.”
- “Conflicts of interest can influence action, but they are not acts and do not constitute a breach of duty” Marc A. Rodwin Professor of Law, Suffolk University Law School (2017)
- Two kinds of conflict of interest:
 - 1) conflicts between an individual’s obligations and their financial or other self-interest;
 - 2) conflicts resulting from an individual’s divided loyalties, dual roles or conflicting duties, sometimes referred to as conflicts of commitments (Peters, 2012).

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Managing Conflicts of Interest Reporting in Healthcare organizations

- IRS requirements
- IRS reporting
- State law requirements
- Initial reporting
- Disclosure? To whom?
- Reporting in minutes
- Policy re contracting, hiring, interaction below board level

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Defining a Problem We Can Solve: Financial Conflicts of Interest and the IRS 990

- IRS Governance Check Sheet 2009 (Form 14114) for use by Revenue Agents
- Written policy
- Written annual disclosures of conflicts
- Record of Recusals
- Have actual or potential conflicts been disclosed
- Whether the written policy has been followed

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Form 990 Review

- Part VI, Section B, of the Governance, Management, and Disclosure Section of the 990:
- “Did the organization have a written conflict of interest policy (12a). If no, go to line 13.”
- If yes on 12a go to line 12b: “Were officers, directors, or trustees, and key employees required to disclose annually interests that could give rise to conflicts?”
- If yes on line 12b, go to line 12c: “Did the organization regularly and consistently monitor and enforce compliance with the policy?”
- If yes, describe in Schedule O how this is done.”

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IRS 990 Instructions (2018)

- Line 12a. Answer "Yes," if as of the end of the organization's tax year the organization had a written conflict of interest policy.
- "A conflict of interest arises when a person in a position of authority over an organization, such as an officer, director, manager, or key employee can benefit financially from a decision he or she could make in such capacity, including indirect benefits such as to family members or businesses with which the person is closely associated. For this purpose, a conflict of interest does not include questions involving a person's competing or respective duties to the organization and to another organization . . ."

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IRS 990 instructions (2018) If "Yes" on line 12c, "describe in Schedule O how this is done."

- Line 12c. " , describe on Schedule O (Form 990 or 990-EZ) the organization's practices for monitoring proposed or ongoing transactions for conflicts of interest and dealing with potential or actual conflicts, whether discovered before or after the transaction has occurred."

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IRS 990 Instructions (2018) If "Yes" on Line 12c, "Describe in **Schedule O** How this is Done."

- The description should include:
 - an explanation of which persons are covered under the policy;
 - the level at which determinations of whether a conflict exists are made;
 - the level at which actual conflicts are reviewed;
 - Also explain any restrictions imposed on persons with a conflict, such as prohibiting them from participating in the governing body's deliberations and decisions in the transaction

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Operational Challenges for Major Academic Medical Centers on Conflicts of Interest

- Written policy, state law requirements
- Reviewing, reporting process on Schedule O of annual IRS 990 (hint: review conflict language before submission)
- Whose job should it be (counsel, compliance, audit committee, compliance committee, secretary)
- Consequences of failure to respond/report
- Systems for capturing conflict reporting
- Record of Recusals-minutes and other decision documents

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Memorial Sloan Kettering - Conflict of Interest Concerns

- Chief Medical Officer Dr. Jose Baselga failed to disclose millions of dollars in payments from drug and healthcare companies in published articles, resigns 9/13/18-NY Times Pro Publica
- “Dr. Baselga and MSK said that he had disclosed his industry relationships to the cancer center.”
- After internal investigation-NY Times reports statement by outside counsel investigator that plans to manage conflicts of interest “were not implemented because it was felt to be unnecessary or because there was a failure to realize that a management plan was needed.”
- Beginning in 2014, NY Times reported that senior executives were no longer required to vet financial relationships with a conflict of interest advisory committee because the hospital felt the committee should not be asked to make decisions about executives to whom they reported.
- 2016 Schedule O “**The Compliance Officer and staff are responsible for administering the conflict of interest program. . .**”
- 2017 Schedule O The Compliance Officer and staff are responsible for administering the conflict of interest program. . .”
- April 2018-Debra Berns has been named as MSK’s Senior Vice President and Chief Risk Officer
- April 2019-new MSK New and Enhanced Conflict of Interest Principles approved

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COMPENSATION

- After COVID19, and federal assistance, expect greater scrutiny of executive pay, physician compensation, “bonuses,” ex gratia and consulting payments
- Schedule J of IRS 990 reporting
- IRS Rebuttable Presumption for Executive Pay
 - Independent comp committee
 - Pay approved in advance by committee
 - Committee obtained and relied upon appropriate comparability data
 - Adequate and timely document of basis for determination
 - Representation on Part VI of IRS 990, questions 15a and 15b

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Pharmaceutical Assistance Programs

- Majority of the patient assistance programs offered by 6 independent charity foundations did not provide financial assistance to uninsured patients based on disclosed patient eligibility criteria.
- The programs were more likely to cover expensive specialty drugs and brand-name drugs than less-expensive brand-name drugs and generic equivalents.

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America's Largest Charities-Pharmaceutical Assistance

- For some patients and their physicians, only source of lifesaving medications
- Favorable tax treatment
- Valuation reporting
- For some companies, part of pricing strategy
- The Assistance Fund settlement - 11/20/2019 \$4 million
- HHS/OIG 5/21/14 Special Advisory Bulletin-Independent Charity Patient Assistance Programs (oig.hhs.gov) (79 FR 31120) Part D focus

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RECENT CORPORATE INTEGRITY PROGRAM

- Recent CIAs-PAP programs (Aventis-Sanofi 2/28/2020; not yet posted on OIG website)
- PAP Compliance Program that outlines acceptable interaction with physicians and healthcare systems.
- Formal action to establish, maintain, and conduct regular oversight of the compliance program.
- Executive compliance committee for management oversight and support for the compliance program.
- Written policies and procedures

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COMPLIANCE PROGRAM FOR PATIENT ASSISTANCE

- How to address “free prescription drugs”
- Sample policies-acceptance, records, reporting
- Applications
- Financial assistance
- Read recent CIAs-limit contact with detail reps and sales/marketing team
- Whose job is it to apply? To assist?

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HOW CAN GOVERNMENT HELP HEALTHCARE DURING COVID19?

- Money
- Information
- Modifying Regulatory Requirements
- Guidance
- Supporting Innovation

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SUPPORTING INNOVATION

- Looking to healthcare sector:
- Are modifications of goals, mission, activities, needed during COVID and after?
- Mergers, affiliations, dissolutions with transfers of assets
- Transactions with related persons to keep organization in existence (documentation important)
- Request release of terms of gift instruments
- Cy Pres relief requests
- Commercial co-venturing, innovative fundraising
- Bankruptcy, creditor resolutions

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WHAT WE ASK FROM HEALTHCARE

- Compliance with statutory protections for employees in local, state, federal law – sick leave, layoff requirements, protective equipment (See “Employment Protections” section of AG Guidance)
- Preservation of charitable assets to protect mission
- Avoidance of actions which will affect perception of charities generally-golden parachutes, change of control payments, salary increases

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INFORMATION: CORONA VIRUS ISSUES FOR CHARITIES

- AG.NY.GOV “Guidance on Coronavirus Resources”
 - Select a Topic drop down menu
- CHARITIESNYS.COM-Guides and Publications-
 - “Guidance for Charitable Nonprofit and Religious Corporations Facing the Challenges of the COVID-19 Pandemic”
 - Charities.bureau@ag.ny.gov - emails to Customer Assistance Unit - can be referred to attorney of the day or accountant of the day
 - Ongoing influential emails-send us your email address, we will put you on list

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THANK YOU FOR YOUR ATTENTION!

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