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Aligning Your Health System's Conflict of Interest Policies with the Physician Payment Sunshine Act

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ALIGNING YOUR HEALTH SYSTEM'S CONFLICT OF INTEREST POLICIES WITH THE PHYSICIAN PAYMENT SUNSHINE ACT

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I. INDUSTRY-PROVIDER RELATIONSHIPS—A MIXED MESSAGE

Advancements in clinical research and patient outcomes are possible when manufacturers of drugs, medical devices, and biologics collaborate with health providers. Relationships between the manufacturers of drugs, devices, biologicals, and medical supplies;[1] and individual physicians and medical centers produce numerous opportunities for the exchange of valuable clinical information and feedback necessary for the advancement of clinical decision-making and patient care.[2] Patients benefit from the first-hand knowledge these practitioners and their respective institutions bring to the practice of medicine.[3] These collaborations, however, often involve financial arrangements, which include financial or professional incentives. These incentives can also pose possible conflicts of interest that can lead to a treatment bias or a clinical decision that favors the use of one device or drug

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1. *See* Social Security Act § 1128G(a)(1)(A)(vii), 42 U.S.C. § 1320a-7h(a)(1)(A)(vii) (2006).

2. *See generally* CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE (Inst. of Med. ed., 2009).

3. *Id.*

over another.[4] In these situations, the practitioners' motives may be in question, and their decisions and viewpoints are potentially compromised.[5]

Conflicts of interest arising from physicians' relationships with industry vary but generally are financial in nature or involve professional gain in the form of increased visibility, peer recognition, or preferential treatment.[6] Financial conflicts of interest occur when physicians are tempted to deviate or do deviate from their professional obligations for economic or other personal gain.[7] "Although most physicians deny that receiving free lunches, subsidized trips, or other gifts from industry has any effect on their practices, research has shown [it] does influence prescribing behavior."[8]

Conflicts can also vary by the physician's practice setting. One survey showed that physicians in solo, two-person, or group practices were significantly more likely to have relationships with industry than were physicians in hospitals or clinics.[9] Possible results of conflicts include prescribing brand-name drugs instead of cheaper and equivalent generic drugs; using drug samples for off-label use; adopting novel treatments before sufficient evidence is available; ignoring evidence-based guidelines; and promoting a "culture of entitlement" based on financial ties with industry.[10] The press has exposed industry and investigators' failure to disclose negative research data or financial relationships.[11] Universities,[12]

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4. *Id.*

5. Troyen Brennan et al., *Health Industry Practices That Create Conflicts of Interest*, 295 JAMA 429, 433 (2006).

6. *Id.*

7. *Id.* at 430.

8. Eric Campbell, *Doctors and Drug Companies—Scrutinizing Influential Relationships*, 357 NEW ENG. J. MED. 1796, 1797 (2007).

9. Eric Campbell et al., *A National Survey of Physician-Industry Relationships*, 356 NEW ENG. J. MED. 1742, 1746 (2007).

10. Campbell, *supra* note 8, at 1796.

11. *See* Brennan, *supra* note 5.

12. *See* AAMC-AAU ADVISORY COMM. ON FINANCIAL CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH, PROTECTING PATIENTS, PRESERVING INTEGRITY, ADVANCING HEALTH: ACCELERATING THE IMPLEMENTATION OF COI POLICIES IN HUMAN

sponsors,[13] and medical journals[14] have policies which require disclosure of all financial relationships in order to assess potential conflicts of interest. For the most part, these relationships and their impact on clinical decision-making are not well known or understood by the public.[15]

Furthermore, disclosure of potential conflicts does not completely resolve the problem.[16] Most patients do not have sufficient scientific knowledge to discern if a possible conflict exists despite disclosure of the relationship.[17] Allowing these conflicts to continue erodes the integrity of the medical profession and undermines society's confidence in health providers and their decisions.

The Physician Payment Sunshine Act,[18] included in the Patient Protection and Affordable Care Act,[19] is intended to eliminate potential conflicts of interest and minimize the bias in treatment choices believed to increase health care costs. Scott & White Healthcare, the largest multidisciplinary health system in Texas, has implemented a conflict of interest policy to assist its employees in identifying conduct that might give rise to a conflict.

SUBJECTS RESEARCH 1 (2008) [hereinafter AAMC-AAU COI POLICIES], http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=6136.

13. *See* Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, 76 Fed. Reg. 53,256 (Aug. 25, 2011) (codified at 42 C.F.R. pt. 50 and 42 C.F.R. pt. 94).

14. *See* Jeffrey M. Drazen et al., *Uniform Format for Disclosure of Competing Interests in ICMJE Journals*, 361 NEW ENG. J. MED. 1896, 1896 (2009), *available at* http://www.nejm.org/doi/full/10.1056/NEJMe0909052.

15. *See* Brennan, *supra* note 5.

16. *Id.* at 431.

17. *Id.*

18. Social Security Act § 1128G, 42 U.S.C. § 1320a-7h (2006).

19. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by the Health Care Education Reconciliation Act, Pub. L. No. 111-152, 98 Stat. 1585 (2010) (codified at 42 U.S.C.A. § 18001 (West 2011)).

II. MAGNITUDE OF THE PROBLEM

Campbell and colleagues reported that in a 2004 study of 3167 physicians, 94 percent of them were involved in some type of relationship with the pharmaceutical industry.[20] Physicians reported receiving food and beverages in the workplace (83 percent); being given drug samples by a manufacturer's representative (78 percent); receiving reimbursement for costs associated with professional meetings or continuing education (35 percent); and receiving payments for consulting, speaking, or enrolling patients in trials (28 percent).[21] Although a follow-up study by the same authors reported a decline in relationships to 84 percent, financial arrangements between industry and physicians remain common and unreported.[22]

Similarly, physician-industry relationships are prevalent in industry-sponsored research. According to the National Institutes of Health, nearly 52 percent of all researchers had relationships with industry in 2007, amounting to nearly double the 28 percent who had such relationships in 1996.[23]

III. EFFORTS TO ADDRESS CONFLICTS OF INTEREST

Eliminating conflicts of interest is of growing interest to policy makers and professional societies.[24] From a policy perspective, the debate centers on the effect of these relationships on patient care and health care costs.[25] A growing number of biomedical ethicists, medical students, journalists, and elected officials have demanded increased transparency through public reporting of financial relationships at institutional, state, and national

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20. Campbell, *supra* note 9, at 1742.

21. *Id.* at 1746.

22. Eric Campbell, *Physician Professionalism and Changes in Physician-Industry Relationships from 2004-2009*, 170 ARCHIVES INTERNAL MED. 1820, 1826 (2010).

23. Scott Harris, *New Conflict of Interest Rules Help Spur Financial Disclosures Online*, ASS'N OF AM. MED. COLLS. (Mar. 21, 2011), https://www.aamc.org/newsroom/reporter/june10/136280/new_conflict_of_interest_rules_help_spur_financial_disclosures.html.

24. Campbell, *supra* note 8.

25. *Id.*

levels.[26] Recently, professional societies, state and federal legislators, and academic-based organizations issued guidelines or regulations to address conflicts of interest and minimize the likelihood of their influence in clinical practice and research.[27]

A. Institute of Medicine

In 2007, the Institute of Medicine ("IOM") appointed the Committee on Conflict of Interest in Medical Research, Education, and Practice to examine conflicts of interest in medicine and to recommend steps to identify, limit, and manage conflicts of interest without negatively affecting constructive collaborations.[28] The IOM report emphasizes that a *preventative* rather than a reactive approach to conflicts of interest is preferred.[29] The Committee recommends: a) disclosure of industry-to-medical-institution financial ties, including academic medical centers, professional societies, patient advocacy groups and medical journals; b) standardization of disclosure content, format, and procedure; and c) enactment of federal legislation that creates a national reporting program requiring pharmaceutical, medical device, and biotechnology companies to make public all payments to physicians, researchers, health care institutions, professional societies, patient advocacy and disease groups, and providers of continuing education.[30]

In addition, the IOM recommends that researchers should not conduct research involving human participants if they have a financial interest in the outcome.[31] Because academic medical centers have a major responsibility for training future physicians and medical staff, their objectivity and scientific integrity is of the utmost importance.[32] To reduce the risk of bias, the IOM recommends that teaching hospitals prohibit faculty from accepting

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26. Eric Campbell, *Public Disclosure of Conflicts of Interest: Moving the Policy Debate Forward*, 170 ARCHIVES INTERNAL MED. 667, 675 (2010).

27. *See* Campbell, *supra* note 8.

28. *See* CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE, *supra* note 2.

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.*

gifts, making presentations, and entering into consulting arrangements not governed by written contracts for specific consulting services to be paid at fair market value.[33] The IOM recommends that health insurers, accrediting bodies, and government agencies develop incentives for policy changes that promote transparency in the development of clinical guidelines and accountability in the nature and disclosure of relationships with industry.[34]

B. Professional Authorities

In 2008, the American Association of Medical Colleges ("AAMC") and the Association of American Universities ("AAU") released the report *Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research.* The report calls on all medical schools and major research universities to develop and implement financial conflicts of interest policies and to refine standards for addressing individual financial conflicts.[35]

In May 2010, the National Institutes of Health ("NIH") issued a notice of proposed rulemaking to edit current regulations to "strengthen accountability and transparency of current financial conflict of interest rules at the government, institutional and investigator level."[36] On a conference call to answer stakeholder questions regarding the proposed rule, NIH Director Francis Collins said that "partnerships between NIH-funded researchers and industry are essential;" the regulations seek to manage these partnerships to reduce financial conflict of interest and intervene when necessary.[37] The proposed changes would increase transparency in financial interest disclosure and enhance compliance and oversight.[38] On August 25, 2011, NIH finalized these proposed changes to the regulations.[39]

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33. *Id.*

34. *See generally* CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE, *supra* note 2.

35. *See* AAMC-AAU COI POLICIES, *supra* note 12.

36. *Financial Conflict of Interest*, U.S. DEP'T OF HEALTH & HUMAN SERVS., http://grants.nih.gov/grants/policy/coi/ (last updated Dec. 2, 2010).

37. Press Briefing, Financial Conflict of Interest Notice of Proposed Rulemaking (May 20, 2010), *available at* http://grants.nih.gov/grants/policy/coi/briefing_transcript-%2805202010%29.htm.

38. Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding Is Sought and Responsible Prospective Contractors, 75

C. State Laws Enacted

In 1993, Minnesota became the first state to mandate industry disclosure of payments related to medical conferences, honoraria, compensation connected to research, or any payment totaling $100 or more to physicians.[40] Other states, including Vermont, Maine, Massachusetts, West Virginia, and the District of Columbia, have implemented guidelines for disclosing physician-industry relationships.[41] A recent review of Vermont's law showed gifting was limited to a few major corporations and that less than two percent of the state's prescribers received 69 percent of the gifts and payments. Companies were notably generous to specialists in psychiatry, endocrinology (e.g., diabetes and metabolic disorders), internal medicine, and neurology.[42] Despite the enactment of a federal disclosure law in 2010 that preempts those portions of state laws that are duplicative or weaker, but does not preempt more restrictive provisions,[43] state lawmakers continue to introduce legislation requiring industry to disclose gifts and compensation to physicians with whom they have consultation and education relationships.[44]

Fed. Reg. 28,688 (proposed May 21, 2010) (to be codified at 42 C.F.R. pt. 50 and 45 C.F.R. pt. 94).

39. Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding Is Sought and Responsible Prospective Contractors, 76 Fed. Reg. 53,256 (finalized Aug. 25, 2011) (codified at 42 C.F.R. pt. 50 and 45 C.F.R. pt. 94).

40. Susan Chimonas et al., *Show us the Money: Lessons in Transparency from State Pharmaceutical Marketing Disclosure Laws*, 45 HEALTH SERV. RESEARCH 98, 98-114 (2010).

41. *Id.* at 98.

42. *Id.*

43. *See* Social Security Act § 1128G(d)(3), 42 U.S.C. § 1320a-7h(d)(3) (2006).

44. *Payment Sunshine: Ohio State Senator Introduces "Payment Disclosure" Duplicative of Federal Law*, POL'Y & MED. (Mar. 17, 2011), http://www.policymed.com/2011/03/physician-payment-sunshine-ohio-state-senator-introduces-payment-disclosure-duplicative-of-federal-law.html.

This patch-work of state laws has led to a call for a national system of disclosure.[45]

D. Federal Legislation Enacted

To provide for a consistent and understandable national system of disclosure,[46] the Physician Payment Sunshine Act ("PPSA") was enacted in the Patient Protection and Affordable Care Act of 2010 ("PPACA").[47] Championed by Senator Chuck Grassley and Senator Herb Kohl,[48] the law requires pharmaceutical and medical device manufacturers (i.e., "industry") to disclose financial relationships with physicians and teaching hospitals. In introducing the bill that was later to become part of the PPACA, Senator Grassley paraphrased Justice Brandeis by stating "Sunlight is the best disinfectant."[49]

The PPSA requires that, beginning no later than March 13, 2013, and on the 90th day of each subsequent year, U.S. manufacturers of covered drugs, devices, biologicals, or medical supplies report electronically to the Secretary of the Department of Health and Human Services ("HHS"), who has delegated this function to the Centers for Medicare & Medicaid Services ("CMS"), the following payments or transfers of value to physicians or teaching hospitals:[50] consulting fees;[51] compensation for services other than

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45. *See* 155 CONG. REC. S788 (daily ed. Jan. 22, 2009) (statement of Sen. Charles Grassley on introduction of S. 301).

46. *Id.*

47. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6002, 124 Stat. 119 (2010), as amended by the Health Care Education Reconciliation Act, Pub. L. No. 111-152, 98 Stat. 1585 (2010) (codified at 42 U.S.C.A. §1320a–7h (West 2011)) (adding section 1128G of the Social Security Act).

48. *Physician Payment Sunshine Act Introduced*, POL'Y & MED. (Jan. 22, 2009), http://www.policymed.com/2009/01/physician-payment-sunshine-act-2009-introduced.html.

49. *See* 155 CONG. REC. S788 (daily ed. Jan. 22, 2009) (statement of Sen. Charles Grassley on introduction of S. 301); *see also* LOUIS D. BRANDEIS, OTHER PEOPLE'S MONEY: AND HOW THE BANKERS USE IT 92 (1914) ("Sunlight is said to be the best of disinfectants . . . .").

50. *See* Social Security Act § 1128G(a)(1)(A), 42 U.S.C. § 1320a-7h(a)(1)(A) (2006).

consulting;[52] honoraria;[53] gifts;[54] entertainment;[55] food;[56] travel;[57] education;[58] research;[59] charitable contributions;[60] royalties or licenses;[61] current or prospective ownership or investment interests;[62] direct compensation for serving as faculty or as a speaker for a medical education

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51. *See* Social Security Act § 1128G(a)(1)(A)(vi)(I), 42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(I).

52. *See* Social Security Act § 1128G(a)(1)(A)(vi)(II), 42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(II).

53. *See* Social Security Act § 1128G(a)(1)(A)(vi)(III), 42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(III).

54. *See* Social Security Act § 1128G(a)(1)(A)(vi)(IV), 42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(IV).

55. *See* Social Security Act § 1128G(a)(1)(A)(vi)(V), 42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(V).

56. *See* Social Security Act § 1128G(a)(1)(A)(vi)(VI), 42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(VI).

57. *See* Social Security Act § 1128G(a)(1)(A)(vi)(VII), 42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(VII).

58. *See* Social Security Act § 1128G(a)(1)(A)(vi)(VIII), 42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(VIII).

59. *See* Social Security Act § 1128G(a)(1)(A)(vi)(IX), 42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(IX).

60. *See* Social Security Act § 1128G(a)(1)(A)(vi)(X), 42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(X).

61. *See* Social Security Act § 1128G(a)(1)(A)(vi)(XI), 42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(XI).

62. *See* Social Security Act § 1128G(a)(1)(A)(vi)(XII), 42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(XII).

program;[63] grants;[64] and any other nature of the payment or transfer of value as defined by the Secretary.[65]

The PPSA requires manufacturers to begin collecting data on payments and transfers of value starting on January 1, 2012.[66] The law also required the Secretary of HHS to establish procedures by October 1, 2011, for manufacturers to disclose information to the Secretary and for the Secretary to make that information available to the public.[67] Included in the disclosure, among other things, is the name of the physician or hospital and the value of the payment.[68] Thus far, neither HHS nor CMS has established those procedures. In its response to a congressional inquiry as to the reason for the missed statutory deadline, CMS Administrator Berwick stated that CMS is working to implement the statutory provision, but did not provide further details on when a proposed rule or any other guidance would be issued.[69] As of the writing of this article, the Office of Management and Budget is reviewing CMS' proposed rule.[70]

The PPSA does not require disclosure if industry provides valuable consideration *indirectly* to a physician or teaching hospital through a third party in conjunction with an activity or service if the manufacturer is unaware of the identity of the recipient or if the product is for patient use and not intended to be sold.[71]

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63. *See* Social Security Act § 1128G(a)(1)(A)(vi)(XIII), 42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(XIII).

64. *See* Social Security Act § 1128G(a)(1)(A)(vi)(XIV), 42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(XIV).

65. *See* Social Security Act § 1128G(a)(1)(A)(vi)(XV), 42 U.S.C. § 1320a-7h(a)(1)(A)(vi)(XV).

66. *See* Social Security Act § 1128G(a)(1)(A), 42 U.S.C. § 1320a-7h(a)(1)(A).

67. *See* Social Security Act § 1128G(c)(1)(A), 42 U.S.C. § 1320a-7h(c)(1)(A).

68. *See* Social Security Act § 1128G(a)(1)(A)(i), 42 U.S.C. § 1320a-7h(a)(1)(A)(i).

69. *See* Letter from Donald Berwick to Sen. Herb Kohl (Oct. 28, 2011), http://policymed.typepad.com/files/sunshineactcmsresponse.pdf.

70. *See List of Regulatory Actions Currently Under Review*, REGINFO.GOV., http://www.reginfo.gov/public/jsp/EO/eoDashboard.jsp (last visited Dec. 12, 2011).

71. *See* Social Security Act § 1128G(e)(10)(A), 42 U.S.C. § 1320a-7h(e)(10)(A).

Payments are excluded if they are less than $10, or in aggregate, amount to less than $100 in the prior year.[72] The law directs CMS to construct an online database and begin posting the collected data beginning September 13, 2013, and on June 30 of each subsequent year.[73] The data collected is to be searchable in a clear, understandable, and downloadable manner.[74] Further, it is to include any penalties imposed or actions taken to ensure compliance.[75] Information relating to relationships formed for clinical research is to be reported separately.[76]

Penalties for noncompliance are monetary and vary depending on the severity and intent of noncompliance.[77] Failing to report correctly the required information in a timely manner may result in fines of up to $10,000, not to exceed $150,000 annually.[78] Knowingly failing to report the required information may result in fines of up to $100,000, not to exceed $1 million annually.[79]

The Act also requires applicable manufacturers and group purchasing organizations (distributors are excluded) to disclose information regarding ownership and investment interests held by a physician (or immediate family member) in the manufacturer or group purchasing organization during the preceding year.[80]

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72. *See* Social Security Act § 1128G(e)(10)(B)(i), 42 U.S.C. § 1320a-7h(e)(10)(B)(i).

73. *See* Social Security Act § 1128G(c)(1)(C), 42 U.S.C. § 1320a-7h(c)(1)(C).

74. *See id.*

75. *See* Social Security Act § 1128G(c)(1)(C)(iv), 42 U.S.C. § 1320a-7h(c)(1)(C)(iv).

76. *See* Social Security Act § 1128G(c)(1)(C)(vi), 42 U.S.C. § 1320a-7h(c)(1)(C)(vi).

77. *See* Social Security Act § 1128G(b), 42 U.S.C. § 1320a-7h(b).

78. *See* Social Security Act § 1128G(b)(1), 42 U.S.C. § 1320a-7h(b)(1).

79. *See* Social Security Act § 1128G(b)(2), 42 U.S.C. § 1320a-7h(b)(2).

80. *See* Social Security Act § 1128G(a)(2), 42 U.S.C. § 1320a-7h(a)(2).

E. Academic Medical Centers Respond

Academic medical centers are uniquely positioned to take a leadership role in eliminating conflicts of interest due to their organizational structure and responsibility for medical training.[81] They also are highly involved in clinical research and are hubs for patient referrals in a wide range of specialties.[82] In response to professional recommendations and in light of state and federal legislation, teaching hospitals are voluntarily implementing conflict of interest policies that address the concerns of policy makers and professional societies.[83]

IV. SCOTT & WHITE HEALTHCARE'S PERSPECTIVE

Scott & White Healthcare, serving patients in a nearly 30,000 square mile area of central Texas, is the largest multispecialty health care system in the state.[84] It owns eight hospitals, affiliates with four more, and recently broke ground for a new hospital in College Station, Texas, all of which cumulatively admit 50,000 total inpatients annually.[85] Scott & White also operates 60 regional primary and specialty care clinics, receiving 2.1 million annual outpatient visits, and a 240,000-member health plan. Scott & White Memorial Hospital also serves as the teaching hospital for the Texas A & M Health Science Center College of Medicine and has a growing division of research conducting in excess of 400 active clinical studies, the majority of which are funded by industry.[86] Founded in Temple, Texas, in 1897, the physician-led nonprofit system employs more than 11,000 staff, including nearly 900 physicians and scientists.[87]

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81. *See* Brennan, *supra* note 5.

82. *Id.*

83. *See, e.g.*, SCOTT & WHITE HEALTHCARE, CONFLICT OF INTEREST POLICY (2011) [hereinafter CONFLICT OF INTEREST POLICY], http://researchers.sw.org/resources/docs/research/COI-Policy-02-01-2011.pdf.

84. *About Us,* SCOTT & WHITE HEALTHCARE, http://www.sw.org/about-us/about-us (last visited Dec. 12, 2011).

85. *Id.*

86. *Id.*

87. *Id.*

In August 2008, The Commonwealth Fund Commission on a High Performance Health System released a report that examined problems engendered by fragmentation in the health care system and offered policy recommendations to stimulate greater organization for high performance.[88] Scott & White was one of 15 case-study sites that the Commission examined to illustrate the six attributes identified as the ideal health care delivery system in a diverse organizational setting.[89]

Scott & White recently took steps to update its conflict of interest policy to address better the disclosure of conflicts and the institution's expectations of relationships with industry. After careful consideration, a revised conflict of interest policy[90] was approved in February 2011. The revised conflict of interest policy attempts to eliminate conflicts of interest in several ways, including: 1) designating a specific department to receive and distribute industry donations of monies or items of value that are intended for educational or developmental use or patient care (e.g., training funds, charitable gifts, medical equipment); 2) requiring prior approval at the department chair level for certain activities such as speaking engagements or industry sponsored travel; 3) prohibiting blatant and direct financial offerings that are not commensurate with an exchange of professional services (e.g., payment for attendance only at an industry-sponsored meeting); and 4) requiring prior approval of agreements with third parties.[91]

Key provisions of the new conflict of interest policy that may be applicable to other teaching hospitals and physician groups include provisions detailing disclosures, prohibited items, allowable items, and other features of the policy.

A. Disclosures

Scott & White employees are required to complete a Conflict of Interest Disclosure Form and keep it up-to-date with current information.[92] Guidelines for relationships and interactions with industry are specific and

88. *See generally* ANTHONY SHIH ET AL., THE COMMONWEALTH FUND COMM'N ON A HIGH PERFORMANCE HEALTH SYS., ORGANIZING THE U.S. HEALTH CARE DELIVERY SYSTEM FOR HIGH PERFORMANCE (2008).

89. *Id.* at 15.

90. CONFLICT OF INTEREST POLICY, *supra* note 83.

91. *Id.*

92. *Id.*

apply to all employees, not just physicians.[93] Relationships involving Scott & White intellectual property are closely scrutinized and any rights, titles, or interests cannot be assigned or transferred without permission.[94]

B. Prohibited Items

Personal gifts from industry are prohibited, including entertainment, recreation, and non-approved travel.[95] Additionally, Scott & White's policy prohibits industry funding for meals on-site, and guidelines are provided for participation in off-site, industry-sponsored programs or meetings where a meal is included.[96] Honoraria for continuing education provided to Scott & White personnel, or provided in a non-Scott & White venue where Scott & White pays travel and expenses, are not permitted.[97] However, if Scott & White does not pay for travel and expenses, then the speaker has the opportunity to accept the honorarium, subject to the department chair's approval.[98]

C. Allowable Items

Donations of equipment and money are allowed but must be coordinated through a central office.[99] Decisions regarding distribution are made by those with no involvement in the donor industry.[100] Drug samples are also permissible but may only be delivered to non-patient care areas in facilities where the samples will be disbursed.[101] Pharmaceutical representatives may not visit with residents or students when delivering the drug samples.[102] The

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93. *Id.*

94. *Id.*

95. *Id.*

96. CONFLICT OF INTEREST POLICY, *supra* note 83.

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.*

102. CONFLICT OF INTEREST POLICY, *supra* note 83.

receipt and distribution of all drug samples, devices, or monetary donations must be carefully documented.[103]

Industry has long been involved in funding educational and research activities for medical staffs.[104] This practice remains permissible at Scott & White if the activity is intended to facilitate training of employees, students, and residents.[105] Funds are collected by the Development Office and distributed by the department chair.[106] The receipt of such donations (but not the amount) may be made public.[107]

Scott & White employees may participate in industry-sponsored speakers' bureaus, but the department chair must pre-approve that participation.[108] Accepting payment solely to attend an industry-sponsored event is prohibited.[109] Industry funding for travel expenses also requires preauthorization by the traveler's department chair and is limited to product evaluations, site assessments, etc.[110] Employees must consult with the Legal Department prior to entering into verbal or written agreements to serve as a speaker or to provide technical skills, consulting, clinical expertise, or related assistance for industry.[111]

D. Other Features of the Conflict of Interest Policy

Integral to the conflict of interest policy is a detailed explanation on how to determine whether a conflict of interest exists.[112] Experience has shown that what may appear to be a risk to one employee goes unnoticed by

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103. *Id.*

104. *Id.*

105. *Id.*

106. *Id.*

107. *Id.*

108. CONFLICT OF INTEREST POLICY, *supra* note 83.

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.*

another.[113] Much care is taken in the conflict of interest policy to parse through the internal processes available to all employees who question their involvement with industry, whether it is seemingly innocent or not.[114] As noted in the IOM report, providing guidance that eliminates a conflict of interest before it happens is preferred over correcting the problem later on.[115]

The integrity of Scott & White's research program and its standing in the academic community is of paramount importance. The conflict of interest policy affirms that the safety and welfare of human subjects involved in clinical trials and the integrity of research at Scott & White should not be subordinated to, or compromised by, financial or other personal interests.[116]

Many of the guidelines for employees conducting research mirror those recommended by the AAMC and AAU.[117] Investigators are encouraged to disclose any situation that could conceivably be viewed as a conflict of interest as early as possible.[118] Scott & White prefers that investigators disclose a potential conflict rather than try and "second guess" whether a conflict exists.[119] Research at Scott & White involves a wide range of funding sources, from governmental agencies to private entities and other universities, making it impossible for any one investigator to know fully of the potential conflicts or risks for the institution at large.[120]

Specifically, investigators must disclose financial interests (including salary, consulting fees, honorarium, stocks, equity interests, ownerships, intellectual property rights, royalties, etc.) for themselves and for their spouses or domestic partners and dependent children.[121] If the financial

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113. *Id.*

114. CONFLICT OF INTEREST POLICY, *supra* note 83.

115. *See* CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE, *supra* note 2.

116. *See* CONFLICT OF INTEREST POLICY, *supra* note 83.

117. *See* AAMC-AAU COI POLICIES, *supra* note 12.

118. CONFLICT OF INTEREST POLICY, *supra* note 83.

119. *Id.*

120. *Id.*

121. *Id.*

interests of other family members are known, they must be disclosed as well.[122] Disclosure is also required of sub-grantees, contractors, or collaborators who conduct research on Scott & White's behalf.[123]

The goal was to design a policy that eliminates the potential bias of working with industry but encourages the advancement in medical knowledge.[124] Thus, practical applications for compliance and reporting were also considered.[125] The conflict of interest policy is to be included in the employee's annual review.[126]

V. PREPARING FOR THE PHYSICIAN PAYMENT SUNSHINE ACT

With the enactment of the Physician Payment Sunshine Act, financial relationships between industry, teaching hospitals, and physicians will be required to be disclosed to the federal government and made public in 2013.[127] While the duty to report rests with industry,[128] teaching hospitals should revise their conflict of interest policies with the goal of addressing the concerns that the federal law intends to correct.

First, teaching hospitals have a heightened interest in eliminating conflicts of interest due to their extensive research interests and responsibilities for training and educating future practitioners. They should establish or revise conflict of interest protocols using professional guidelines such as the AAMC-AAU recommendations.[129] Although industry has the duty to disclose financial relationships under the new federal law, teaching hospitals share an equal, if not greater, responsibility for upholding patient welfare, maintaining research integrity, and lowering health care costs by virtue of the high frequency of direct patient contact in such hospitals and their responsibility for training future physicians and medical staff.

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122. *Id.*

123. *Id.*

124. CONFLICT OF INTEREST POLICY, *supra* note 83.

125. *Id.*

126. *Id.*

127. *See* Social Security Act § 1128G(c)(1)(C), 42 U.S.C. § 1320a-7h(c)(1)(C) (2006).

128. *See* Social Security Act § 1128G(c)(1)(A)(i), 42 U.S.C. § 1320a-7h (c)(1)(A)(i).

129. *See* AAMC-AAU COI POLICIES, *supra* note 12.

Second, teaching hospitals should identify a physician who is responsible for explaining and securing support for the conflict of interest policy across the institution. Scott & White has found that physicians are receptive to their peers and can offer each other guidance and feedback on the policy's implementation and adoption. Conflict of interest policies should not be viewed as a deterrent, but rather an important step in maintaining an institution's commitment to high-quality, unbiased patient care.

Third, institutions should share their conflict of interest policy with industry partners and work collaboratively to ensure that the policies are understood and enforced. Collaborative relationships and frequent, open-door discussions may also ensure that industry's disclosure to CMS under PPSA will be accurate and fair. Establishing these relationships early on will help expedite the "review and correct"[130] process CMS will provide to industry and teaching hospitals prior to the public release of registry data.

Lastly, institutions should educate their consumers, referring physicians, and patients about their relationships with industry and help them understand both the importance of these relationships and the steps being taken to avoid concerns. One approach Scott & White plans to utilize is disclosing physician-industry relationships on the "Find-a-Provider" portion of its website.[131] Institutions should also be prepared to offer assistance interpreting CMS data once it is publicly available in a manner that conveys a sense of trust, accountability, and a commitment to patient welfare.

VI. CONCLUSION

Eliminating conflicts of interest in physician-industry relationships is of growing importance. With the enactment of the Physician Payment Sunshine Act, teaching hospitals should develop conflict of interest policies that strengthen the collaborative exchange of knowledge with industry, while eliminating the opportunity for bias in clinical decision-making and research. Scott & White Healthcare's efforts as an operator of a major teaching hospital in Temple, Texas, are one way hospitals and physician groups may move in this direction.

130. *See* Social Security Act § 1128G(c)(1)(D), 42 U.S.C. § 1320a-7h(c)(1)(D).

131. *Provider Directory,* SCOTT & WHITE HEALTHCARE, http://www.sw.org/provider-search (last visited Dec. 12, 2011).