

Corporate Integrity Agreement Awareness Survey

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Introduction

Corporate Integrity Agreements

Corporate Integrity Agreements (CIAs), issued by the Office of the Inspector General (OIG) of the US Department of Health & Human Services (HHS), are designed to address fraud in Medicare or Medicaid reimbursement. CIAs typically include hefty fines, repayment of ill-gotten gains, and require the implementation and monitoring of company-wide remediation initiatives. Failure to comply with CIA obligations may result in additional fines or exclusion from participation in government reimbursement programs, regardless of corporate headquarters location (U.S. or international).

Impact on Sponsored Publications

CIAs can directly impact company-sponsored publications by mandating specific policies for publication planning, needs assessments, and adherence to International Committee of Medical Journal Editors (ICMJE) criteria. Our objective was to assess the level of understanding about CIAs among publication professionals.

Methods

- 25 pharma-company CIAs were reviewed prior to the development of this survey. CIA documents were accessed via a publicly available website created by the OIG (<https://oig.hhs.gov/compliance/corporateintegrity-agreements/cia-documents.asp>).
- Introductory e-mails containing links to a 12-question electronic survey were sent to ISMPP members listed as employees of pharmaceutical companies.
- The survey queried all respondents about their tenure in publication planning, their general knowledge of CIAs, and whether their company was currently under a CIA.
- The survey then narrowed to only those respondents working in companies operating under a CIA. This group was queried about training they received and specifics about the impact of the CIA on sponsored publications.
- 73 subjects started the survey, with 61% (44/73) reporting at least 6 years of publication planning experience. Responses are reported for all questions.
- Due to the relatively small number of responses, it was not possible to correlate with any degree of statistical significance, the tenure of the respondent with their knowledge of a company's CIA.

Results

Impact of Company's Headquarters on a CIA

Background: A CIA may be entered into by any entity participating in Medicare, Medicaid, or other federal and state health care programs regardless of headquarters location.

- 70% (51/73) knew this, while 30% (22/73) were either unsure or assumed that CIAs only applied to US companies.

Who Can Issue a CIA?

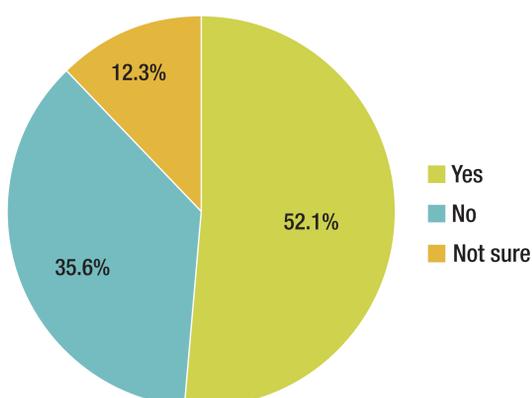
Background: OIG has permissive exclusion authority under 42 USC §1320a-7b(7) to pursue false reimbursement claims submitted in violation of the False Claims Act or Civil Monetary Penalties Law.

- 70% (51/73) knew that CIAs are issued by OIG/HHS, while the remainder did not know or were unaware of this fact.

CIA Status

52% (38/73) reported operating under a CIA, 36% (26/73) were not, and 12% (9/73) were unsure.

Is your company presently operating under a CIA?

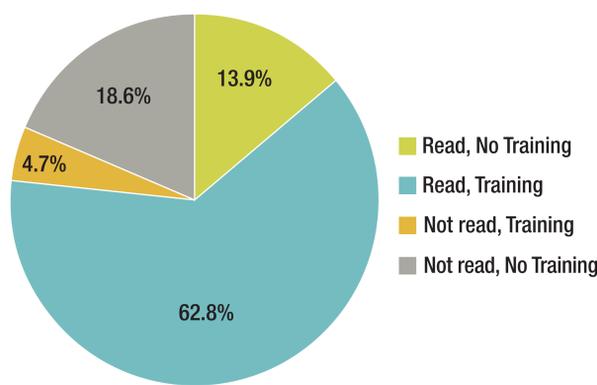


Have You Read or Received Training on Your Company's CIA?

Background: CIAs require at least one hour of "General Training" for all company employees during each one-year reporting period. General Training, at a minimum, must explain the CIA requirements and compliance program including the Code of Business Conduct. In addition, company employees must annually receive "Specific Training" that is relevant to his or her specific job responsibilities. New hires must receive training within 30 days of commencing employment.

- Almost 19% (8/43) had not read their CIA, nor had they received training. 77% (33/43) stated that they had read their company's CIA. 67% (29/43) said that they received formal training, 84% of which (30/36) took place within the past year.

Have you personally read or received formal training on your company's CIA?

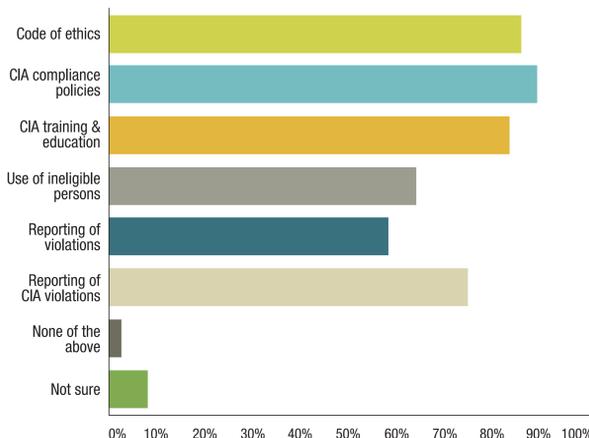


Required Written Standards

Background: CIAs require the company to implement written standards, policies, and procedures for activities and issues including a code of ethics, CIA compliance, training and education, independent review organizations, ineligible persons, and the reporting of CIA violations.

- Awareness was highest for code of ethics (86%, 31/36), policies and procedures, and training and education (83% 30/36), but somewhat lower for independent review organizations (64%, 23/36), personnel ineligible to participate in Federal programs (58%, 21/36), and reporting of CIA violations (75%, 27/36).

Which of the following written standards are addressed within your CIA?



CIAs with Obligations Relating to Sponsored Publications

Background: Not every CIA addresses sponsored publications, however clauses relating to sponsored publications are appearing with greater frequency as CIAs become more comprehensive in nature.

- 78% of respondents (28/36) reported that their company's CIA specifically addressed sponsored publications.

ICMJE

Background: ICMJE is the only publication criteria mentioned in any of the 25 CIAs reviewed for this survey. GPP, CONSORT, and WAME were not mentioned in any CIA.

- Of the 78% of respondents (28/36) reporting that their company's CIA specifically addressed sponsored publications, 65% (17/26) knew that ICMJE criteria were specifically mentioned within their CIA.

Publication Plans, Needs Assessments, Budgets

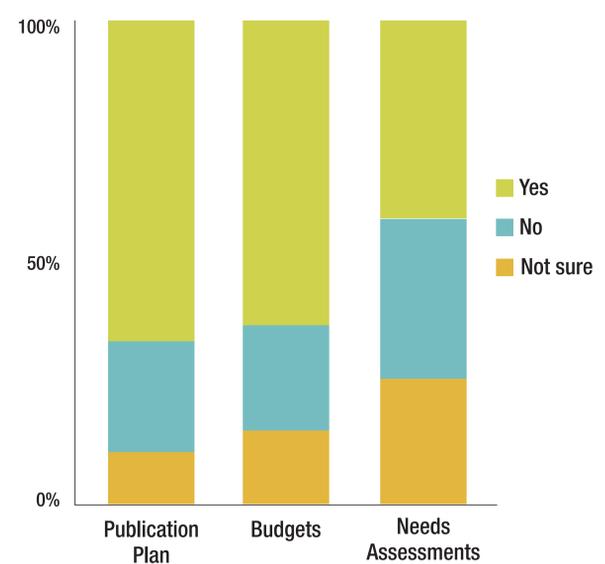
Background: To ensure that publication activities and related events are used for legitimate purposes, recent CIAs have required a global publication plan for each government reimbursed product. The annual plans should identify the business needs for and the estimated numbers of various publication activities. The annual publication plan shall also identify the budgeted amounts to be spent on publication activities.

Recent CIAs have also required the completion of a needs assessment as well as written author agreements prior to the retention of an author. The needs assessment shall provide specific details including a description of the proposed work to be done, type of work product to be generated, purpose for the work, and any fees to be paid to the author as determined by a pre-set rate structure.

Finally, U.S. compliance personnel must be involved in the review and approval of such annual publications plans, including any modification of an approved plan.

- Roughly two-thirds of respondents (18/27) stated that their CIA required an annual publication plan and an annual needs assessment (17/27). Fewer than half the respondents (11/27) stated that their CIA required an annual publications budget.

Does your CIA address publication plans, budgets, needs assessments?



Discussion

CIAs provide clear direction for publication planning, needs assessments, and adherence to ICMJE guidelines. Failure to comply may trigger additional fines and sanctions regardless of headquarters location.

Our survey indicates that additional educational efforts may be warranted. While two-thirds of respondents were knowledgeable about most obligations required by their company's CIA, ignorance of the law by one-third of respondents highlights a need for more aggressive educational efforts and an opportunity for Certified Medical Publication Professionals to help increase awareness and compliance. For example:

- Participate in the development and implementation of mandated annual training specific to publications sponsored by their employer.
- Provide added diligence to assure that training schedules are adhered to and that newly hired staff members are trained on the company's CIA obligations in a timely manner.
- Maintain proper documentation of all agreements with external authors and researchers.
- Serve as internal advocates for ethical publication practices as outlined in ICMJE.

By virtue of their professional training and certification, and the fact that every CIA can easily be found online, Certified Medical Publication Professionals have both an ethical and professional obligation to assure that companies comply with CIA mandates.

Suggested Reading

- OIG Corporate Integrity Agreement home page: <https://oig.hhs.gov/compliance/corporateintegrity-agreements/cia-documents.asp>.
- ICMJE home page: <http://www.icmje.org>
- Rodino FJ, Corporate Integrity Agreements: What They Say About Publications, Publication Planning, Transparency, and ICMJE, *Therapeutic Innovation & Regulatory Science* January 2013 vol. 47 no. 1 50-56



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