

Corporate Integrity Agreements: What They Say About Publications, Publication Planning, Transparency, and ICMJE

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Abstract

Corporate integrity agreements (CIAs) have become a significant means of compliance enforcement for the Office of the Inspector General (OIG) of the US Department of Health and Human Services. The objective of this review is to present in a factual manner common clauses from recent CIAs that affect publications, publication planning, and transparency. Fourteen CIAs issued to biopharmaceutical companies from January 1, 2009, through July 31, 2012, were reviewed. All documents were publicly accessible on the OIG website. Eight CIAs included similar verbiage relating to industry-sponsored publication activities and transparency. Each included specific recommendations for author agreements, publication plans, needs assessments, publication monitoring, posting of study results, and disclosure of relationships with authors. The publishing behaviors OIG seeks to effect are consistent with currently accepted guidelines described in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, as prepared by the International Committee of Medical Journal Editors (ICMJE) and Good Publication Practices for Communicating Company-sponsored Medical Research (GPP2), as well as added training, monitoring, and reporting requirements. By making clear the importance of publication planning, needs assessments, adherence to ICMJE, and reporting of physician payments, and by becoming readily accessible to everyone, CIAs provide the industry not only with clear direction for, but also an expectation of, responsible behavior when it comes to sponsored medical publications.

Keywords

CIA, ICMJE, GPP2, OIG, compliance

Introduction

Off-label promotion activities, illegal inducements to prescribe a particular product, and lack of transparency have captured the attention of regulators and legislators. Corporate integrity agreements (CIAs) have become a significant means of compliance enforcement for the Office of the Inspector General (OIG), of the US Department of Health & Human Services (HHS). Over the past 3 years, many CIAs have included specific wording regarding sponsored medical publications. Noncompliance with CIAs can result in significant fines and sanctions.

Corporate Integrity Agreements

A CIA is a compliance obligation negotiated between the OIG and health care providers and other entities such as biopharmaceutical companies, equipment manufacturers, and hospitals. CIAs are negotiated as part of the settlement of federal health

care program investigations arising under a variety of civil false claims statutes. False claims submitted in violation of the False Claims Act or Civil Monetary Penalties Law give rise to the OIG's permissive exclusion authority under 42 USC § 1320a-7b(7).¹

A CIA outlines the obligations an entity agrees to as part of a civil settlement. An entity such as a biopharmaceutical company, a hospital, or an equipment supplier, consents to the CIA obligations in exchange for the OIG's agreement that it won't seek to exclude the entity from participation in Medicare, Medicaid, or

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other federal and state health care programs. The CIAs have common elements, but each one is tailored to address the specific facts of the case. CIAs are often drafted to recognize the elements of a pre-existing compliance program.²

CIAs have been entered into by biopharmaceutical companies of all sizes and include companies with 2010 revenues below US\$50 million and also over US\$50 billion. The more comprehensive CIAs include, but are not limited to, requirements for written policies and procedures, staff training, compliance monitoring and status reports, and independent reviews. The typical term of a comprehensive CIA is 5 years; fines for individual companies have exceeded US\$3 billion.

CIA documents are accessible by the public via a website created by OIG (<https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp>). Documents are listed alphabetically and linked to downloadable PDF files. The website also includes FAQs and other useful background information.

The primary objective of this paper is to assess common clauses from recent CIAs that affect publications, publication planning, and transparency. It is not the intent of the author to render opinions on specific corporate policies or to suggest remedial actions necessary to reduce the likelihood of a CIA. Those are policies that require the input of management, corporate legal counsel, marketing, medical affairs, and publications professionals.

Methods

The author reviewed the OIG CIA website and found a total of 178 CIAs entered into between January 1, 2009, through July 31, 2012. In addition, the author reviewed the websites of the US Department of Justice and Department of Health and Human Services for official press releases relating to fines imposed upon the recipients of each CIA.

The CIAs were entered into by a wide range of organizations that received payments from Medicare, including hospitals, group practices, individual physicians, universities, municipalities, equipment manufacturers, and biopharmaceutical companies. Of the 178 CIAs entered into during this period, 14 involved biopharmaceutical companies. PDFs of the 14 biopharmaceutical CIAs were download from the website and reviewed individually for common clauses relating to publications and disclosure.³⁻¹⁶ Eight CIAs contained wording specific to sponsored publication activity and are the focus of this paper. For 1 CIA, a company had voluntarily adopted a publications protocol transparency initiative and agreed to continue the initiative throughout the duration of their CIA. The 5 remaining CIAs were issued for infractions that did not include sponsored publication activity.

Results

Author Agreements

The 8 CIAs contained similar, if not exact, wording regarding publication activities. They required the company to enter written agreements with authors describing the scope of work to be performed, the fees to be paid in connection with the publication activities, and compliance obligations of the authors. The CIAs allow for payment of authors “according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by the company.”

Physician Payment

All require independent review of physician payments. Companies are required to post quarterly, 6-month, and annual listings of physicians and related entities (eg, hospitals, group practices, etc) who received payments directly or indirectly from the company. For each physician and related entity, the physician payment listing must include the physician’s name, name of related entity (if applicable), city and state that the physician or the related entity, and the aggregate value of the payments in the preceding quarters or year. If payments for multiple physicians have been made to one related entity, the aggregate value of all payments to the related entity will be reported.

Disclosure

Each CIA requires the company to adopt policies to ensure that all authors of biomedical manuscripts to fully comply with criteria from the International Committee of Medical Journal Editors (ICMJE) regarding authorship and disclosure of their relationship with the company and to disclose any potential conflicts of interest, including any financial or personal relationships that might be perceived to bias the work.¹⁷ In fact, ICMJE is the only non-OIG publication guidance referenced within the CIAs. The CIAs require that the company amend its policies relating to authors to explicitly state its requirement about full disclosure by authors consistent with the requirements of any health care institution, medical committee, or other medical or scientific organization with which the authors are affiliated. In addition, for any amendments to its contracts with authors, the company is asked to include an explicit requirement that authors disclose in their manuscripts, journal submissions, and elsewhere as appropriate or required, any potential conflicts of interest, including their financial or personal relationship with the company, the names of any individuals who have provided editorial support for any manuscript or other publication, and all funding sources for the study or publication.

Publication Plans

To ensure that publication activities and related events are used for legitimate purposes in accordance with company policies and procedures, 7 of the CIAs specifically require the establishment of an annual publication planning process. The publication plan should identify the business needs for and the estimated numbers of various publication activities as well as identify the budgeted amounts to be spent on publication activities. To ensure that publication activities and related events are used for legitimate purposes, the company's compliance personnel must be involved in the review and approval of the annual publications plans, including any modification of an approved plan.

Needs Assessments

All 8 CIAs state that the company shall establish a needs assessment process for publication activities. The needs assessment shall provide specific details about the publication activities to be performed (including a description of the proposed work to be done, type of work product to be generated, and the purpose for the work). It is clearly stated that needs assessments should be completed prior to engaging an author, and that any deviations from the needs assessments are subject to review by the company's compliance personnel. CIAs are process-oriented and do not specifically define the term *need*. This may be to allow sponsors and authors some degree of flexibility to address the disparate needs of a wide range of audiences.

Training

To ensure a top-to-bottom understanding of the CIA requirements, each include an extensive discussion on company-wide training of corporate officers and staff members. Topics include general training on the CIA requirements and company compliance program as well as training that is applicable to the specific job functions of the employee. Trainers must be knowledgeable about the subject area of the training, including applicable federal health care program and FDA requirements. Each individual who is required to attend training shall certify, in writing, or in electronic form, that he or she has received the required training, the type of training, and date received.

Publication Monitoring

All 8 CIAs require the establishment of a publication monitoring program through which the companies are required to conduct audits of an agreed-upon number of publication activities during a specific reporting period. The monitoring program selects publication activities for review both on a risk-based targeting approach and on a random sampling approach. The monitoring program reviews needs-assessment documents,

contracts, proposal documents, approval documents, contracts, payments and materials relating to the activity, and resulting work product to assess whether the activities were conducted in a manner consistent with the company's policies and procedures. Results from the monitoring program, including potential violations, must be compiled and reported to the company's compliance personnel review and appropriate follow-up.

Independent Review Organizations

All 8 CIAs require the engagement of an independent review organization (IRO). An IRO may be an accounting, auditing, or consulting firm engaged to evaluate systems, processes, policies, procedures, and practices relating to the CIA. The OIG has issued guidances that summarize OIG's views on the relevant principles that should be used to assess the independence and objectivity of an IRO that performs CIA reviews.¹⁸ CIAs require that each IRO furnish a certification that the IRO has evaluated its professional independence and objectivity with respect to the review being performed for the provider and that the IRO has concluded that it is independent and objective. CIAs also give the OIG discretion to reject a provider's choice of IRO or to require a provider to retain a new IRO if the OIG determines the IRO is not independent.

Discussion

While CIAs are negotiated as part of the settlement of federal health care program investigations arising under a variety of civil false claims statute, their wording specific to publication activities warrants comparison to ICMJE and the Good Publication Practices for Communicating Company-sponsored Medical Research (GPP2).¹⁹ There are many good publication guidances available. However, ICMJE and GPP2 are the most relevant for comparison with a CIA; ICMJE is the only publication guidance cited within the CIAs, and GPP2 is the only publication guidance specific to industry-sponsored medical publications. Table 1 provides a summary comparison of 16 key clauses from CIAs, ICMJE, and GPP2.

CIAs, ICMJE, and GPP2

Both CIAs and GPP2 agree that authors are expected to comply with ICMJE guidelines for authorship. All 3 agree that authors should fully disclose within their manuscripts their funding sources and any potential financial and nonfinancial conflicts of interest, and acknowledge any editorial support they may have received. They also concur that the sponsor should post all applicable clinical trials in a public clinical trials registry.

Table 1. Comparative clauses.

Clause	CIA ³⁻¹⁶	ICMJE ¹⁷	GPP2 ¹⁹
Author agreements	Sponsor shall require all authors to enter written agreements describing the scope of work to be performed, the fees to be paid in connection with the publication activities, and compliance obligations of the authors.	Not specifically addressed.	Written agreements for articles and presentations from research studies should be made at the earliest opportunity.
Scope of work	See author agreements.	Not specifically addressed.	Not specifically addressed
Author access to data	Not specifically addressed.	Researchers should not enter into agreements that interfere with their access to all of the data and their ability to analyze them independently, and to prepare and publish manuscripts. Provides suggested wording declaring that an author had full access to all of the data in the study.	Sponsors must provide authors and other contributors with full access to study data and should do so before the manuscript writing process begins or before the first external presentation of the data.
Authorship	All authors of biomedical manuscripts are expected to fully comply with the ICMJE criteria regarding authorship.	Authorship credit should be based on (1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.	Recommends using criteria for authorship described in ICMJE.
Guarantorship	Not specifically addressed.	The persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information.	One author (identified as guarantor) should take overall responsibility for the integrity of a study and its report.
Contributorship	Not specifically addressed.	All contributors who do not meet the criteria for authorship, and who provided only general support should be listed in an acknowledgments section.	Clear, concise descriptions of the role of each contributor during preparation of the article or presentation should be acknowledged within the article or presentation. Provides specific examples of proper acknowledgements.
Author payments	Authors shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis.	Not specifically addressed.	May be appropriate to reimburse reasonable out of pocket expenses incurred by contributors or pay for specialized services such as statistical analysis. Reimbursement details must be disclosed. Recommends that no honoraria are paid for authorship of peer reviewed articles or presentations.
Author disclosures	Sponsor shall include an explicit requirement that authors disclose in their manuscripts, journal submissions, and elsewhere as appropriate or required, any potential conflicts of interest, including their financial or personal relationship with the sponsor, the names of any individuals who have provided editorial support for any manuscript or other publication, and all funding sources for the study or publication.	ICMJE developed a uniform disclosure form. Investigators must disclose potential conflicts to study participants and should state in the manuscript whether they have done so.	Authors should disclose financial and non-financial relationships that could inappropriately influence, or seem to influence professional judgment.
Editorial support	See author disclosure.	Authors should identify individuals who provide writing or other assistance and disclose the funding source for this assistance.	Particular care should be taken to ensure appropriate acknowledgment of the contributions made by medical writers and to describe their funding.
Funding source	See author disclosure.	Funding sources should be identified and authors should describe the role of the study sponsor, if any, in study design, collection, analysis, and interpretation of data; writing the report; and the decision to submit the report for publication.	Funding sources, if any, for the research and for the article or presentation, such as for the work of a professional medical writer should be acknowledged.
Clinical trials registration	Sponsor shall register all clinical studies and report results of such clinical studies on the National Institutes of Health (NIH)-sponsored website (www.clinicaltrials.gov) in compliance with all current federal requirements.	ICMJE member journals will require, as a condition of consideration for publication in their journals, registration of the clinical trial in a public trials registry.	Research sponsors must register and post all applicable clinical trials according to the definitions and timelines required of them by relevant legislation and guidelines.
Publication plan	Sponsor shall establish a process to develop annual plans that identify the business needs for and the estimated numbers of various publication activities. The annual publications plan shall also identify the budgeted amounts to be spent on publication activities.	Not specifically addressed.	A publication plan should support authors and publication steering committees in their efforts to ensure appropriate, efficient, and complete communication of results. Provides suggestions for items to be included in plan.
Needs assessments	A needs assessment process shall be established for publication activities. A needs assessment shall be completed prior to contracting with an author. The needs assessment shall include a description of the proposed work to be done, type of work product to be generated, and the purpose for the work.	Not specifically addressed.	Not specifically addressed.
Manuscript structure	Not specifically addressed.	ICMJE provides extensive guidance for the preparation, structure, and submission of scientific manuscripts.	Not specifically addressed.
Duplicate publication	Not specifically addressed.	ICMJE views duplicate publication of original research as particularly problematic because it can result in inadvertent double-counting or inappropriate weighting of the results of a single study, which distorts the available evidence.	Premature and duplicate publication should be avoided.
Publication monitoring	Sponsor shall establish a Publication Monitoring Program through which it shall conduct audits for each reporting period. Publications will be reviewed both on a risk-based targeting approach and on a sampling approach.	Not specifically addressed.	Not specifically addressed.

CIA, corporate integrity agreement; ICMJE, Uniform Requirements for Manuscripts Submitted to Biomedical Journals, as prepared by the International Committee of Medical Journal Editors; GPP2, Good Publication Practice for Communicating Company-sponsored Medical Research.

*CIA*s and ICMJE

ICMJE guidelines were designed primarily to help authors and editors in their mutual task of creating and distributing accurate, clear, easily accessible reports of biomedical studies. Unlike CIAs and GPP2, ICMJE was not designed to specifically address sponsored medical publications. CIAs defer to ICMJE on the issue of authorship and do not specifically address guarantorship or contributorship. CIAs do not address manuscript preparation and submission, statistics, referencing, or duplicate publication, whereas ICMJE discusses these activities in great detail.

*CIA*s and GPP2

There are several areas in which CIAs and GPP2 overlap. Both make clear the need for agreements between the sponsor and the author, and both address payments to authors. The need for a publication plan is also highlighted by both CIAs and GPP2. Interestingly, only CIAs address the issue of needs assessments—a core element of continuing medical education (CME) programs—for specific publication activities.

The US Department of Justice has added training, monitoring, and reporting requirements to these standards of good publication practice and incorporated them into its compliance agreements.

Collectively, CIAs, ICMJE, and GPP2 provide the biopharmaceutical industry with clear guidance for ethical behavior when it comes to sponsored medical publications. The inclusion of good publishing practice recommendations within CIAs underscores the importance of comprehensive, objective, and responsible publication planning.

Financial Impact of a CIA

The 14 CIAs reviewed include criminal fines, civil fines, and forfeiture of assets totaling more than US\$11 billion.²⁰⁻³³ The 8 CIAs assessed for this study accounted for more than US\$8.5 billion. Depending upon the offenses, recovered fines are often distributed to the Medicare program and to Medicaid states. In several instances, payments of US\$10 million or more have been made to individuals under the whistleblower provision of the False Claims Act. Penalties for violating a CIA are not specifically stated, but the implication is clear that exclusion from participating in Medicare, Medicaid, and other federal and state health care programs is possible for repeat offenders.

Critics of Publication Planning and ICMJE

Publication planning and ICMJE have both had their critics. Sismondo and colleagues³⁴⁻³⁶ have equated publication planning with commercial exploitation. Matheson³⁷ views ICMJE

as inadequate and recommends changes to ICMJE authorship principles. Bosch and colleagues³⁸ suggest challenging authorship of industry-sponsored manuscripts in the US courts, but never mentions the role of CIAs as a remedy for past ethical breaches. Despite the efforts of these individuals to portray publication planning in a negative light, the Office of the Inspector General of the US Department of Justice, through the enforcement of CIAs, recognizes that publication planning and ICMJE can help to ensure that industry-sponsored publication activities remain ethical and transparent.

Providing Balance

CIAs provide all stakeholders with a responsible, ethical, and balanced approach to sponsored medical publications. They address the concerns of those who equate sponsored publications with commercial exploitation by requiring training of all company personnel and by spelling out requirements for needs assessment, transparency, and publication monitoring processes. They also help to address claims that companies are hiding data by requiring the posting of all clinical trials on government websites, by requiring the implementation of publication plans to help assure that all clinical data is published, and through the engagement of independent review organizations.

Conclusion

Discouraging kickbacks and off-label promotion and promoting transparency are key drivers of CIAs. CIAs have become a significant means of enforcement of specific behaviors on the part of biopharmaceutical companies. The publishing behaviors OIG seeks to effect are consistent with currently accepted publishing guidelines described in ICMJE and GPP2. By making clear the importance of publication planning, needs assessments, adherence to ICMJE, and reporting of physician payments, and by making them readily accessible to everyone, CIAs provide the industry not only with clear direction for, but also an expectation of, responsible behavior when it comes to sponsored medical publications. Proactively adopting the principals necessary to conform to CIAs is a decision that requires the input of management, corporate legal counsel, marketing, medical affairs, and publications professionals.

Declaration of Conflicting Interests

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