Mini Summit V: Dissecting Recent CIAs and Review of Draft Model CIA

Faculty

John Bentivoglio | Skadden
Regina Cavaliere | KPMG
Jennifer McGee | Otsuka

Pharmaceutical Compliance Congress
November 8, 2018

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Topics for Discussion

- Recent Trends in Pharma and Device CIAs
- New CIA Provisions
  - New or Revised Definitions
  - Written Standards
  - Board and Management Accountability
  - CCO Role / Relationship to Legal Department
  - Financial Recoupment
  - Independent Charitable Foundation (ICF) Controls
  - Risk Assessment
  - Arrangements Database
- OIG's New Risk and Transparency Initiatives
- Toward a More Effective Model CIA

Recent Trends in Pharma and Device CIAs

Analysis of Settlements | 2015-2018 (to date)

	Settlements		
	Total	Criminal	Civil
Total 2015	13	3	13
Total 2016	11	3	9
Total 2017	9	3	9
Total 2018 (to date)	4	0	4
Total 2015-18	37	9	35

Analysis of Settlements & CIAs | 2015-2018 (to date)

Type of Case	37 Total Settlements	9 New CIAs	9 Prior CIAs	Exclusion	Notes
Criminal Cases	**9**	**3** • Olympus • B Braun • Aegerion	**2** • J&J (McNeil) • Genzyme	**1** • Warner-Chilcott (parent, Allergan, was under prior CIA)	Two criminal cases with no CIA (Baxter and Biocompatibles) involved nonpromotional FDCA violations)
Civil-only; $100 million or more	**6** • Novartis (390) • Shire (350) • Celgene (280) • Wyeth (785) • Mylan (465) • UT (210)	**2** • Mylan • UT	**3** • Shire (prior CIA) • Novartis (addendum to prior CIA executed) • Wyeth (prior CIA)		Celgene case was originally declined by DOJ and pursued by relator's counsel; DOJ only intervened at end of case
Civil-only; $50 million-$99 million	**3** • Salix ($54) • Novo-Nordisk ($59) • Genentech ($67)	**0**	**1** • Salix (via Valeant)		Salix was in process of being acquired by Valeant (which was under a CIA at time of settlement)
Civil-only; less than $50 million	**19** • Pfizer ($23.85) and others	**4** • Daiichi ($39) • Respironics ($34.8) • CardioSys ($8) • Pfizer (ICFs)	**3** • AstraZeneca • Inspire (bought by Merck) • Forest		Pfizer had multiple prior CIAs Cases with no CIA: Medtronic (twice); Atrium (GMP); NuVasive (promotion of surgical devices); Qualitest (GMP); Coloplast; Holister; Acclarent (purchased by J&J); Baxter (GMP); Sanofi-Pasteur (only VA issues); Galena (divested product in question)

New Provisions in Recent Pharma and Device CIAs

Recent Trends: Definitions

"Covered Persons" limitations for employees, contractors, subcontractors, agents, and other persons:

- Excluded if they work < 160 hours **per Reporting Period**

> c. all contractors, subcontractors, agents, and other persons (including contract sales personnel) who perform any of the Covered Functions on behalf of Aegerion, and in that capacity either: (i) interact directly with healthcare professionals (HCPs), healthcare institutions (HCIs), Payors (as defined below in Section II.C.6) or consumers; or (ii) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by an Aegerion employee who is a Covered Person prior to execution or dissemination.
>
> Notwithstanding the above, the term Covered Persons does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours during a Reporting Period, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the Reporting Period.

- Excluded if they work < 160 hours **per calendar year** (and other carve-outs) (*Novartis*)
- No exclusions (*United Therapeutics)*

Recent Trends: Definitions (cont'd)

Expanded Definition:

- **Product Related Functions** – Section II.C.5:

  The term "Product Related Functions" includes: (a) the preparation or external dissemination of non-promotional materials about Government Reimbursed Products, including those functions relating to any applicable review committees and to Novartis' Medical Affairs Department (Medical Affairs), **and any materials about Government Reimbursed Products that are provided by Novartis to Specialty Pharmacies or created by Specialty Pharmacies at the direction of Novartis for use in connection with a Fee-For-Service Arrangement (as defined below);** (b) contracting with healthcare professionals ("HCPs") in the United States to conduct post-marketing clinical trials and post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; and (d) activities related to the submission of information about Government Reimbursed Products in government-listed compendia (such as Drugdex or other compendia of information about Government Reimbursed Products).

  (emphasis added)

Recent Trends: Definitions (cont'd)

Patient Assistance Related Functions:

"includes: all activities, systems, processes, and procedures relating to the following: (a) any grants, charitable contributions, or cash or in kind donations provided by Pfizer or any entity acting on behalf of Pfizer to any independent third-party patient assistance program (Independent Charity PAP) (collectively, "Independent Charity PAP Related Functions"); and (b) the operation of, or participation in, any patient assistance program by Pfizer of any entity acting on behalf of Pfizer that provides free drugs to patients, including Federal health care program beneficiaries (i.e., Pfizer's internal free drug program) or programs to provide financial assistance to patients in the form of cost-sharing assistance (i.e., co-pay coupons or co-pay card) (programs described under Section II.C.5.b shall be collectively referred to as "Pfizer PAPs").

Recent Trends: Definitions (cont'd)

- **Specialty Pharmacies – Novartis Addendum Section II.C.10:**

  "…pharmacies located in the United States and licensed and regulated by one or more state pharmacy board(s) that dispense specialty prescription drugs (those pharmaceuticals that typically require special handling, administration, or inventory management), primarily by mail or third party delivery services; to patients with chronic conditions, acute events, or complex or high-cost therapies; and that provide services including patient education, support and/or coordination with patients and prescribers."

Is this the first official definition of what constitutes a "Specialty Pharmacy" from HHS-OIG?

If so, here are the key attributes of a Specialty Pharmacy:

1) Drugs dispensed have special requirements (e.g., handling, administrative, inventory); and
2) Drugs shipped to patient (primarily); and
3) Patients have chronic conditions or an acute event or the drug therapy is complex or expensive; and
4) Pharmacy provides other services to patients and prescribers

Recent Trends: Definitions (cont'd)

- **Arrangements – Novartis Addendum Section II.C.8 outlines the 2 types:**

  "Arrangements" shall mean every arrangement or transaction that: involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Novartis and any Specialty Pharmacy and is related to the dispensing of a Government Reimbursed Product by the Specialty Pharmacy. Arrangements involving Novartis' payment to a Specialty Pharmacy for services provided shall be referred to as "Fee for Services (or FFS) Arrangements." Those Arrangements under which Novartis provides a pricing term (such as a discount) to the Specialty Pharmacy shall be referred to as "Discount Arrangements."

Recent Trends: Written Standards

Excerpts from Pfizer CIA

C. The scope of this CIA shall be governed by the following definitions:

3. The term "Promotional Functions" includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to Pfizer's review and approval processes for promotional materials and any applicable review committee(s).

B. Written Standards.

e. appropriate ways to conduct Promotional Functions in compliance with all: (i) applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute and the False Claims Act; and (ii) applicable Food and Drug Administration (FDA) requirements.

Recent Trends: Board Accountability

- *Board of Directors Compliance Obligations.* The Board shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. **The Board must include independent (i.e., non-executive) members**.

  The Board shall, at a minimum, be responsible for the following:

  a. Meeting at least quarterly to review and oversee Aegerion's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

  b. Submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the Compliance Program and in support of making the resolution below during each Reporting Period; and

  c. For each Reporting Period of the CIA, adopting a resolution signed by each individual member of the Board, summarizing its review and oversight of Aegerion's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

  At minimum, the resolution shall include the following language:

  "The Board of Directors has made a reasonable inquiry into the operations of Aegerion's Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Aegerion has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement."

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Aegerion.

Aegerion shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations of this CIA, within 15 days after such a change.

[**NOTE**: *Pfizer's CIA is limited to "compliance with Federal health care program requirements and the requirements of this CIA." Compliance with "FDA requirements" is out of scope except for written standards and training.]*

Recent Trends: Board Accountability (cont'd)

- *Board of Directors Compliance Obligations.* The Board shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. **The Board must include independent (i.e., non-executive) members.**

  The Board shall, at a minimum, be

  a. Meeting at least quarterly to re… of the Compliance Officer and C…

  b. Submitting to OIG a description… the engagement of an indepen… support of making the resolutio…

  c. For each Reporting Period of th… review and oversight of Aegeric… obligations of this CIA.

  At minimum, the resolution shall in…

  "The Board of Directors has made a reaso… of the Compliance Officer and the Compli… knowledge, Aegerion has implemented ar… requirements, and the obligations of the …

  If the Board is unable to provide su… written explanation of the reasons why i… effective Compliance Program at Aegeric…

  Aegerion shall report to OIG, in w… that would affect the Board's ability to p… after such a change.

  [NOTE: Pfizer's CIA is limited to "compli… CIA." Compliance with "FDA requireme…

Additional Requirement: Board Must Retain Compliance Expert to Conduct Effectiveness Review in 1st Reporting Period

Excerpt from United Therapeutics:

d. For the first Reporting Period of the CIA, the Board shall retain an individual or entity with expertise in compliance with Federal health care program requirements (Compliance Expert) to perform a review of the effectiveness of United Therapeutics' Compliance Program (Compliance Program Review). The Compliance Expert shall create a work plan for the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to United Therapeutics' compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of United Therapeutics' compliance program. A copy of the Compliance Program Review report shall be provided to OIG in each Annual Report submitted by United Therapeutics. In addition, copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to OIG upon request.

Recent Trends: Board Member Training

- Requirements for training on "the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity." May use outside compliance expert.

2. *Board Member Training*. Within 120 days after the Effective Date, Aegerion shall provide at least two hours of training to each member of the Board. This training shall address Aegerion's CIA requirements and Compliance Program, the corporate governance responsibilities of Board members, and the responsibilities of Board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of OIG's guidance on Board member responsibilities.

New members of the Board shall receive the Board Member Training described above within 30 days after becoming a Board member or within 120 days after the Effective Date, whichever is later.

- *NOTE: Not all CIAs require training that addresses the "CIA requirements and Compliance Program"*

Recent Trends: Role of Chief Compliance Officer

Excerpts from United Therapeutics CIA

1. *Compliance Officer*. Within 90 days after the Effective Date, United Therapeutics shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of United Therapeutics; shall report directly to the President of United Therapeutics; and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for United Therapeutics. The Compliance Officer shall be responsible for, without limitation:

a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;

b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of United Therapeutics and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by United Therapeutics as well as for any reporting obligations created under this CIA.

Recent Trends: Financial Recoupment

H. Employee and Executive Incentive Compensation Restriction Program and Executive Financial Recoupment Program.

Aegerion agrees to develop and maintain throughout the term of the CIA policies and procedures for sales personnel (including sales representatives, sales managers, rare disease partners, and sales trainers) that shall: (1) be designed to ensure that financial incentives do not improperly motivate sales personnel to engage in improper promotion, sales, or marketing of Aegerion's products; (2) include mechanisms, where appropriate, to exclude from incentive (variable) compensation any sales under circumstances indicating that improper promotion of Aegerion's products may have occurred; and (3) provide for the internal review and analysis of all variable compensation prior to payment (Variable Compensation Program). The specific terms and conditions of the Variable Compensation Program are described in Appendix C to this CIA.

Aegerion agrees to establish and maintain throughout the term of this CIA a financial recoupment program (Executive Financial Recoupment Program) that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay for a Covered Executive if the individual or his/her subordinates engaged in significant misconduct as described in greater detail in Appendix C. The specific terms and conditions of the Executive Financial Recoupment Program are described in Appendix C.

Recent Trends: Financial Recoupment Flashback (cont'd)

GSK Excerpt:

H. Employee and Executive Incentive Compensation and Recoupment Policies and Practices.

Pursuant to its existing Patient First program, GSK agrees that it will not provide financial reward (through compensation, including incentive compensation or otherwise) or discipline (through tangible employment action) its prescribing-customer-facing field sales professionals (pharmaceutical sales representatives) or their direct managers based upon the volume of sales of GSK products within a given employee's own territory or the manager's district. The Patient First program includes evaluations for sales representatives based on business acumen, customer engagement, and scientific knowledge about GSK's products. GSK shall continue its Patient First Program, or a substantially equivalent program, during the term of this CIA. GSK commits to maintaining for at least the duration of the CIA, absent agreement otherwise with the OIG, the restrictions on such tangible employment decisions set forth in its Use of Territory/Individual Sales Data policy.

In addition, GSK shall establish and maintain throughout the term of this CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay (i.e., annual bonus, plus long term incentives) for an executive who is discovered to have been involved in any significant misconduct (Executive Financial Recoupment Program). This financial recoupment program shall apply to both covered executives who are either current GSK employees or who are former GSK employees at the time of a Recoupment Determination. The specific terms and conditions of the Executive Financial Recoupment Program are set forth in Appendix E. GSK commits to maintaining an Executive Financial Recoupment Program consistent with the terms of Appendix E for at least the duration of the CIA absent agreement otherwise by the OIG.

PAR Excerpt:

H. Employee and Executive Incentive Compensation Restriction Program and Executive Financial Recoupment Program.

Par agrees that Par will maintain policies and procedures that shall (1) be designed to ensure that financial incentives do not inappropriately motivate sales representatives or their direct managers to engage in improper promotion, sales, and marketing of Par's pharmaceutical products; and (2) include mechanisms, where appropriate, to exclude from incentive compensation any sales that may indicate off-label promotion of Par's pharmaceutical products.

Effective April 1, 2013, Par agrees that it will not provide financial reward (through compensation, including incentive compensation or otherwise) or discipline (through tangible employment action) its prescribing-customer-facing field sales professionals (pharmaceutical sales representatives) or their direct managers based upon the volume of sales of any non-generic megestrol acetate product within a given employee's own territory or the manager's district (Employee and Executive Incentive Compensation Restriction Program). Par shall maintain its Employee and Executive Incentive Compensation Restriction Program, or a substantially equivalent program, during the term of this CIA. Par commits to maintaining for at least the duration of the CIA, absent agreement otherwise with the OIG, these restrictions on incentive compensation.

In addition, Par agrees that by 2014, except as may be required in connection with local controlling law, Par shall establish and maintain throughout the term of the CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay for an executive who is discovered to have been involved in any significant misconduct (Executive Financial Recoupment Program). This financial recoupment program shall apply to Covered Executives (as defined in Appendix D) who are either current Par employees or who are former Par employees at the time of a Recoupment Determination. The specific terms and conditions of the Executive Financial Recoupment Program are set forth in Appendix D. Par commits to maintaining an Executive Financial Recoupment Program consistent with the terms of Appendix D for at least the duration of the CIA absent agreement otherwise by the OIG.

Recent Trends: Risk Assessment

Traditional "RAMP"

D. Risk Assessment and Mitigation Process.

Within 120 days after the Effective Date, Aegerion shall implement a centralized annual risk assessment and mitigation process (RAMP) as further described in this Section III.D and Appendix B. The RAMP shall require compliance, legal and business unit leaders, at least annually, to evaluate and identify risks associated with Aegerion's participation in Federal health care programs and the risks associated with each Government Reimbursed Product, including risks associated with the sales, marketing, and promotion of such products. Based on the outcomes of the risk-identification component of the RAMP, Aegerion legal, compliance and other personnel shall centrally develop and implement specific plans designed to mitigate or reduce the identified risks. The risk mitigation plans shall be developed annually and a plan shall be developed for each Government Reimbursed Product. Aegerion shall implement the risk mitigation plans and shall track the implementation of the mitigation plans. The RAMP shall be reviewed by the IRO, and the IRO review of the process is described in more detail in Appendix B. Aegerion shall maintain the RAMP for the duration of the CIA.

Recent Trends: Risk Assessment (cont'd)

Excerpt from United Therapeutics CIA: Still titled a RAMP but focus is on a 5-part internal review process (leverages internal audit)

D. Risk Assessment and Mitigation Process.

Within 120 days after the Effective Date, United Therapeutics shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each of United Therapeutics' Government Reimbursed Products and with applicable Federal health care program requirements. The risk assessment and internal review process shall require compliance, legal, and department leaders, at least annually, to: (1) identify and prioritize risks associated with each Government Reimbursed Product, including risks associated with the sales, marketing, and promotion of such products and risks associated with United Therapeutics' operation of any patient assistance program and the company's arrangements and interactions with any Independent Charity PAPs, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. United Therapeutics shall maintain the risk assessment and internal review process for the term of the CIA.

Recent Trends: Risk Assessment (cont'd)

Excerpt from Pfizer CIA – 3 parts

D. Risk Assessment and Internal Review Process.

Within 120 days after the Effective Date, Pfizer shall develop and implement a centralized annual Risk Assessment and Internal Review Process to identify and address risks associated with each of Pfizer's Government Reimbursed Products and with applicable Federal health care program requirements. The Risk Assessment and Internal Review Process shall require compliance, legal, and department leaders at least annually, to: (1) identify and prioritize risks associated with each Government Reimbursed Product, including risks associated with the sales, marketing, and promotion of such products and risks associated with Pfizer's operation of any Patient Assistance Related Function and the company's arrangements and interactions with any Independent Charity PAPs, (2) develop mitigation plans in response to the results of risk assessments performed, and (3) track the implementation of the mitigation plans in order to assess the implementation, status, or effectiveness of such plans. Pfizer shall maintain the Risk Assessment and Internal Review Process for the term of the CIA.

CIA Requirements for Relationships with ICFs

- Three recent CIAs (Aegerion, UT and Pfizer) require controls around relationships with ICFs
- Key provisions:
  - Definitions (e.g., patient assistance activities)
  - Oversight of ICF activities vested in non-commercial committee or team
  - Strict separation from commercial organization
  - Implementation of annual ICF budget process
  - Review and approval of funding initial and supplemental funding requests based on standardized, objective and written criteria
  - Limits on data and information received from ICF
  - ICF/PAP monitoring requirements

Recent Trends: Arrangement (Contracting) Controls

Excerpts from Novartis CIA Addendum

1. *II.C.8:* "Arrangements" shall mean every arrangement or transaction that: involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Novartis and any Specialty Pharmacy and is related to the dispensing of a Government Reimbursed Product by the Specialty Pharmacy. Arrangements involving Novartis' payment to a Specialty Pharmacy for services provided shall be referred to as "Fee-for-Service (or FFS) Arrangements." Those Arrangements under which Novartis provides a pricing term (such as a discount) to the Specialty Pharmacy shall be referred to as "Discount Arrangements."

   a. *Arrangements Procedures*. To the extent not already accomplished, within 120 days after the Addendum Effective Date, Novartis shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute or the regulations, directives, and guidance related to the statute (Arrangements Procedures). These procedures shall include the following:

      i. creating and/or maintaining a centralized tracking system for all existing and new or renewed Arrangements (Arrangements Tracking System);

      ii. tracking remuneration to and from all parties to Arrangements;

Recent Trends: Arrangement (Contracting) Controls (cont'd)

iii. tracking service and activity logs to ensure that parties to the Arrangement are performing the services required under the applicable Arrangement(s) (if applicable);

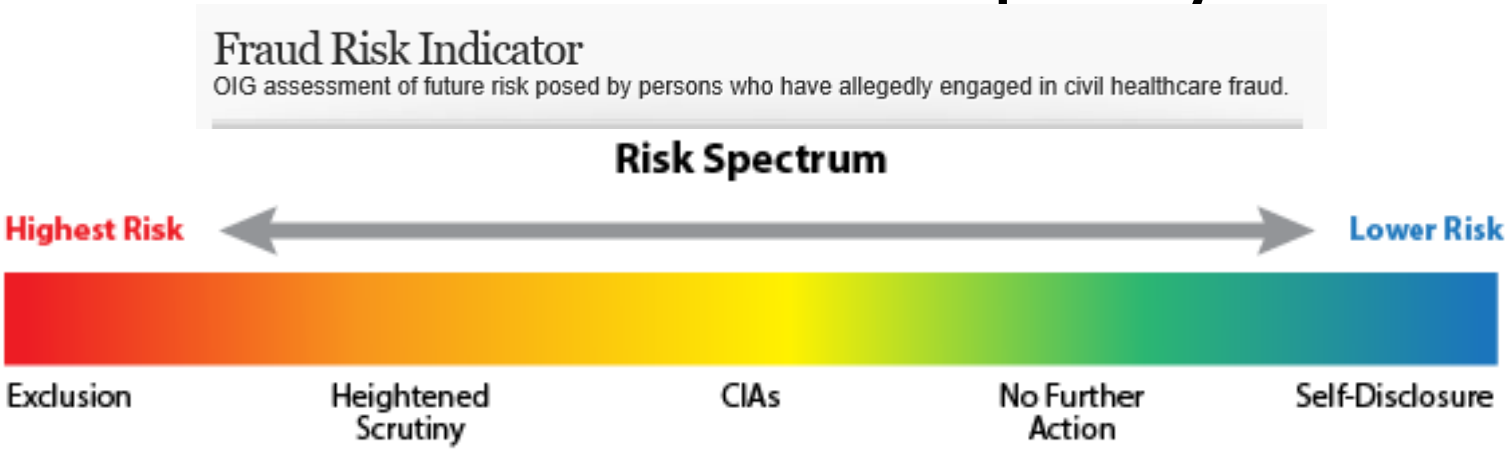
iv. establishing and implementing a written review and approval process for all Arrangements, the purpose of which is to ensure that all new and existing or renewed Arrangements do not violate the Anti-Kickback Statute and that includes at least the following: (i) a legal review of all Arrangements by counsel with expertise in the Anti-Kickback Statute, (ii) for FFS Arrangements, a process for specifying the business need or business rationale for each service provided under the FFS Arrangement and determining and documenting the fair market value of the remuneration specified in the FFS Arrangement;

v. requiring the Chief Compliance Officer (or designee) to review the Arrangements Tracking System, internal review and approval process, and other Arrangements Procedures on at least an annual basis and requiring the Chief Compliance Officer to provide a report on the results of such review to the Compliance Committee; and

vi. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events.

HHS OIG's New CIA Risk and Transparency Initiatives

HHS OIG's New CIA Risk and Transparency Initiatives



The government's primary civil tool for addressing healthcare fraud is the False Claims Act (FCA). Most FCA cases are resolved through settlement agreements in which the government alleges fraudulent conduct and the settling parties do not admit liability. Based on the information it gathers in an FCA case, OIG assesses the future trustworthiness of the settling parties (which can be individuals or entities) for purposes of deciding whether to exclude them from the Federal healthcare programs or take other action. OIG applies published criteria to assess future risk and places each party to an FCA settlement into one of five categories on a risk spectrum. OIG uses its exclusion authority differently for parties in each category (as described in the criteria and below). OIG bases its assessment on the information OIG has reviewed in the context of the resolved FCA case and does not reflect a comprehensive review of the party. Because OIG's assessment of the risk posed by a FCA defendant may be relevant to various stakeholders, including patients, family members, and healthcare industry professionals, OIG makes public information about where a FCA defendant falls on the risk spectrum.

Risk Categories

- Highest Risk - Exclusion
- High Risk - Heightened Scrutiny
- Medium Risk - CIAs
- Lower Risk - No Further Action
- Low Risk - Self-Disclosure

Source: https://oig.hhs.gov/compliance/corporate-integrity-agreements/risk.asp

Toward a More Effective Model CIA

Model Pharma / Device CIA

By John Bentivoglio, Jennifer Bragg and Elizabeth Berry

Skadden

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
[COMPANY]

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Model CIA: 10 Ways to Improve CIA Template

1. Use modern commercial contracting conventions
2. Organize around elements of an effective compliance program
3. Strengthen reporting to Boards of Directors
4. Streamline policies requirements
5. Eliminate disincentive to update policies
6. Update training to incorporate adult learning techniques
7. Adapt monitoring and auditing requirements to reflect company's current and future activities
8. Incorporate risk assessment
9. Provide avenue to raise IRO concerns
10. Provide incentives to adopt programs beyond minimum CIA requirements

Appendix:

Independent Charitable Foundation Requirements

Recent Trends: New Provisions: ICF (Co-Pay) Controls

J. Independent Charity Patient Assistance Program Activities

To the extent that United Therapeutics makes monetary donations to Independent Charity PAPs, it shall comply with the provisions of this Section III.J.

1. *Role and Responsibilities of the Independent Charity Interaction Team.* Within 90 days after the Effective Date, United Therapeutics shall vest sole responsibility and authority for budgeting and other donation related activities relating to Independent Charity PAPs in its existing Grants Review Committee and Compliance Officer (referred to herein as the "Independent Charity Interaction Team").

The Independent Charity Interaction Team shall operate separately and independently from United Therapeutics' commercial organization. For purposes of this CIA, the "commercial organization" shall be defined to include the sales, marketing, and similar commercial business units of United Therapeutics. United Therapeutics' commercial organization shall have no involvement in, or influence over, the review, approval, or implementation of any budget or other decisions or activities relating to donations to Independent Charity PAPs.

Recent Trends: New Provisions: ICF Controls (cont'd)

Sole responsibility and authority for communicating with Independent Charity PAPs regarding United Therapeutics' donations to such PAPs shall be vested in the Independent Charity Interaction Team. United Therapeutics' commercial organization shall not communicate with, influence, or be involved in communciations with, or receive information from Independent Charity PAPs.

2. *Budgeting Process*. Within 90 days after the Effective Date, United Therapeutics' Independent Interaction Team shall establish a budget process to be followed for United Therapeutics' donations to Independent Charity PAPs. The Independent Charity Interaction Team shall propose an annual budget for donations to Independent Charity PAPs based on objective criteria in accordance with general guidelines approved by the legal department with input from the compliance department. The commercial organization shall have no involvement in the budget process, and the budget to be used for donations to Independent Charity PAPs shall not be based on monies allocated to the Independent Charity Interaction Team from the commercial organization.

Recent Trends: New Provisions: ICF Controls (cont'd)

United Therapeutics shall approve the annual budget for donations to Independent Charity PAPs at a level within the organization above the commercial organization (e.g., at the executive level). After the annual budget is approved, the Independent Charity Interaction Team shall have sole responsibility for allocating the approved budget across donations to Independent Charity PAPs and to any disease state fund established by the Independent Charity PAP.

The Independent Charity Interaction Team shall have sole responsibility for assessing requests for additional or supplemental funding from Independent Charity PAPs outside of the annual budget. Such requests shall be assessed against standardized, objective criteria established by the Independent Charity Interaction Team. United Therapeutics legal and compliance personnel shall also be involved in the review and approval of requests for additional/supplemental funding. The purpose of this review shall be to ensure that any supplemental funding to the Independent Charity PAP is provided in accordance with applicable Federal health care program requirements, OIG guidance, and United Therapeutics Policies and Procedures.

Recent Trends: New Provisions: ICF Controls (cont'd)

3. *Criteria Relating to Donations to Independent Charity PAPs.* Within 90 days after the Effective Date, the Independent Charity Interaction Team (with input from the legal department and compliance departments) shall establish standardized, objective written criteria that govern donations to Independent Charity PAPs and any specific disease state funds of such PAPs. The criteria shall be designed to ensure that the Independent Charity PAP does not function as a conduit for payments or other benefits from United Therapeutics to patients and does not impermissibly influence patients' drug choices.

United Therapeutics' Independent Charity Interaction Team shall gather information about Independent Charity PAPs and their disease funds in a manner that does not exert or attempt to exert any direct or indirect control over the entity operating the PAP or over its assistance program. United Therapeutics shall not influence or attempt to influence, directly or indirectly, the identification, delineation, establishment, or modification of, or the parameters relating to, any disease fund by the Independent Charity PAP.

Personnel from United Therapeutics' legal and compliance departments shall review all proposed donations and arrangements between United Therapeutics and any Independent Charity PAP. United Therapeutics shall not make donations to any Independent Charity Group or to any disease state fund of an Independent Charity PAP until after the legal and compliance review has occurred.

Recent Trends: ICF / PAP Review Procedures

PAP Review Program. Within 90 days after the Effective Date, Aegerion shall establish an Independent Charity PAP Review Program (PAP Review Program) through which it shall conduct annual audits of donations to Independent Charity PAPs. The number of programs to be audited shall be determined by OIG after taking into account the number of Aegerion's donations to Charity Entities and to the disease state funds of those entities. The PAP Review Program shall judgmentally select donations for review.

Monitoring Personnel shall review, to the extent available: 1) budget documents; 2) documents relating to any decision to provide donations to a particular Independent Charity PAP; 3) the written agreements in place between Aegerion and the Charity Entities; 4) correspondence and other documents reflecting communications and interactions between the Aegerion and the Independent Charity PAPs; and 5) any other available information relating to the arrangements and interactions between Aegerion and the Independent Charity PAPs. The purpose of the PAP Review Program shall be to assess whether the activities were conducted in a manner consistent with Aegerion's Policies and Procedures described above and with OIG Guidance. Results from the PAP Review Program, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.