INTER-AMERICAN COALITION FOR BUSINESS ETHICS
MEDICAL TECHNOLOGY SECTOR

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Inter-American Coalition for Business Ethics in the Medical Technology Sector

Los Angeles | 6 June 2022

Welcome Members

COALICIÓN INTERAMERICANA POR LA ÉTICA EMPRESARIAL
SECTOR DE TECNOLOGÍA MÉDICA

COALIZÃO INTERAMERICANA PARA ÉTICA EMPRESARIAL
SETOR DE TECNOLOGIA MÉDICA

INTER-AMERICAN COALITION FOR BUSINESS ETHICS
MEDICAL TECHNOLOGY SECTOR

General Information

- ***Virtual guests:***
  - Please keep yourself muted throughout the duration of the session.
  - Use the chat box for any questions or comments.
  - Once the Ethics Coalition session is complete, please use a different link to connect to our afternoon session for the Regulatory Coalition
  - *If you have any technical difficulties accessing the meetings during the day of the event, please contact: hugo@perlitteras.com; ablasi@crowell.com*

- ***In-person guests:***
  - Masks are available upon request, please let a team member know.
  - Simultaneous translation is offered for all hybrid Coalition activities. Please connect your device to the meeting Zoom (such as a cell phone or laptop) along with headphones. *Please keep your mic muted once connected.*
  - Restrooms
  - Guest Wifi Network: *Pipeline*
    - Username: *guest@crowell.com*
    - Password: *Pochard*

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Opening Welcome Remarks

Sujata Dayal, Vice President & Global Chief Compliance Officer, Medline Industries

Chair, AdvaMed Chief Compliance Officer's Committee

Sergio Pinto, Senior Director for Third Party Ethics and Compliance

Chair, AdvaMed Latin America Compliance Working Group

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Coalition Progress Report & What to Expect for the Summit of the Americas

Andrew Blasi
Executive Secretary, Inter-American Coalition for Business Ethics

- *2021 Coalition and Member Achievements*
- *2022 and 2023 Coalition Action Plan Priorities*
- *ABD Policy Recommendations for the 9th Summit of the Americas*
- *9th Summit of the Americas – Anticipated Political Commitments on Democratic Governance and Health*

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2021 Coalition & Member Achievements

INTER-AMERICAN COALITION FOR BUSINESS ETHICS
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Updated Brand

AMÉRICAS ÉTICA EN LA SALUD
FORO VIRTUAL

AMÉRICAS ÉTICA NA SAÚDE
FÓRUM VIRTUAL

AMERICAS HEALTH ETHICS
VIRTUAL FORUM

17-18 AGOSTO 2021 | 17-18 AUGUST 2021

Region's largest-ever health ethics program (including first regional dialogue b/w private sector and health authorities on building integrity into regulatory systems)

Brazil's first national consensus framework for ethical collaboration across the health system – over 40 parties

IDB

CAPRODI
CÁMARA ARGENTINA DE REACTIVOS PARA DIAGNÓSTICO

Dispositivos Médicos
Tus necesidades, nuestra prioridad
CANIFARMA

New Members Associations

New MedTech codes of ethics in Brazil, Chile, and USA

Expanded IDB partnership, including on third-party risk and codes of ethics

2022 & 2023 Coalition Action Plan Priorities

PRIMARY OUTCOMES (2022-2023):

- Demonstrate implementation of each industry association code by majority of companies + annual trainings
- Launch national-level, multi-stakeholder partnerships (consensus frameworks)
- Launch resource guide on government strategies to encourage ethical conduct

ADDITIONAL OUTCOMES (2022-2023):

- Review/refine Bogota Principles
- Demonstrate each industry association has established an ethics committee that holds routine sessions
- Support/promote impact assessment on the benefits of ethical conduct and integrity in the MedTech sector
- Pursue consensus framework to drive multi-stakeholder alignment on ethical practices
- Launch distributor compliance portal and certification system
- Launch network of MedTech experts to develop ethics curriculum and implement via trainings

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ABD Policy Recommendations: 9th Summit of the Americas

- Encouraging the private and public sectors to adopt **comprehensive integrity mechanisms** to drive a **high-standard, level playing field**.

- Implementing **Good Regulatory Practices (GRP)** as a practical method for increasing transparency and integrity.

- Fostering **region-wide adoption of codes of conduct** by relevant industry associations and demonstrating **effective implementation** by their member companies.

- Conducting, directly and through international organizations, **targeted capacity building** for the implementation of codes of conduct by relevant industry associations and ethics and compliance programs by **third-party intermediaries**.

- Developing **public-private partnerships and collective action initiatives** to prevent and fight corruption, including **consensus frameworks** for ethical collaboration across diverse stakeholders.

Anticipated Political Commitments @ Summit

Health *(first-ever @ Leader level)*

- Harmonization and convergence of regulations governing health systems
- Examine financing mechanisms
- Promoting ethical conduct to prevent corruption
- Implement intl benchmarks for good regulatory practices and modernized procurement systems

Democratic Governance *(first since Lima Declaration in 2018)*

- Strengthen confidence in democracies by fulfilling commitments on transparent governance, good regulatory practices, anticorruption, and rule of law
- Measures to encourage the reporting of irregularities and acts of corruption
- Establish public-private partnerships in the prevention of and fight against corruption, and encourage the private sector to take collective action to conduct business with transparency and accountability

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Presentation and Q&A Session on the AdvaMed Code of Conduct

Christopher White
General Counsel & Chief Policy Officer,
Advanced Medical Technology Association
(AdvaMed)

AdvaMed Code of Ethics in 2022

Christopher White
General Counsel & Chief Policy Officer
AdvaMed

Presentation and Q&A Session on AdvaMed Code of Ethics – 6 June 2022

10th Meeting of the Inter-American Coalition for Business Ethics in the MedTech Sector

AdvaMed
Advanced Medical Technology Association

AdvaMed Code of Ethics in 2022

- **Board Approved on 15 March 2022**
- **Revised Code effective 1 June 2022**

AdvaMed Code of Ethics

Legal & Compliance / March 15, 2022

Download

The AdvaMed Code provides medical technology companies with guidance on ethical interactions and relationships with health care professionals, based on the cornerstone values of innovation, education, integrity, respect, responsibility, and transparency. A company that adopts the Code is strongly encouraged to submit to AdvaMed an annual certification stating that the company has adopted the Code and has implemented an effective compliance program.

AdvaMed Code of Ethics CERTIFIED

Ask me more about our New Code of Ethics, Effective June 1, 2022

AdvaMed
Advanced Medical Technology Association

Healthcare Professional Meetings

- U.S Department of Health and Human Services (HHS) Office of Inspector General (OIG) Special Fraud Alert on Speaker Programs – Noted special risks in presentations by HCPs at company-sponsored events.

- **AdvaMed Code Updates:**
  - Meeting Guidelines
    - ✓ Virtual Contexts Recognized
    - ✓ Use of Discretion in Provision of Alcohol
  - Consulting Arrangements
    - ✓ Appropriate Documentation Principle
  - Entertainment & Recreation
    - ✓ Inconsistency with Appropriate Business Purpose Stated

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Advanced Medical Technology Association

Value-Based Frameworks

- HHS OIG's Value-Based Arrangement Regulation – Safe harbor protection for certain value-based arrangements, including limited patient engagement technology safe-harbor.

- **Code Updates**
  - Purpose of Medical Technology
    - ✓ Data-Driven Devices & Solutions Preamble
    - ✓ Member Participation & Purpose Recognized
  - Glossary of Terms
    - ✓ Value-Based Care Defined

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Advanced Medical Technology Association

New Code Tools & Resources

- Six New FAQs Added to Code
- Board-Approved Standalone Guidance on Value-Based Arrangements

FREQUENTLY ASKED QUESTIONS

9 May Companies Provide Alcohol at Company-Conducted Programs & Meetings?

Decisions to provide modest refreshments, including alcohol, must comply with the requirements of Section VII of the Code. In furthering the Code's commitment to responsible business practices, Companies also may consider adopting controls around the provision of alcohol at Company-Conducted Programs and Meetings. For example, considering government guidance, Companies may adopt per-person drink limits, per-drink spend limits, limitations on the types of alcohol permitted (e.g., beer and wine only), or disallow alcohol at certain events

AdvaMed Best Practices Guidance on Value-Based Arrangements

March 15, 2022

Background

The U.S. health care system is transitioning from a fee-for-service and fee-for-product (volume-based) model to a value-based paradigm to deliver more coordinated, high-quality, affordable health care. Under the traditional fee-for-service / product framework, services and products are paid for on a utilization basis. The fraud and abuse laws – specifically, the federal Anti-Kickback Statute (AKS) – evolved under this framework, in which remunerative arrangements between providers and manufacturers were scrutinized for their potential to encourage overutilization, increase federal health care costs, and improperly influence medical decisions.

Zoom

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New Code Tools & Resources

- SFA-Related Code Revisions Benchmarking Report
- Medical Education & Training Illustrative Best Practices

4. Does your company provide and cover the cost of alcohol at Company-Conducted Programs & Meetings?

4a. *(if yes)* Which of the following controls does your company apply to providing and covering the cost of alcohol at Company-Conducted Programs & Meetings?

PROACTIVE COMPLIANCE QUESTIONS

Consider documenting how attendees are selected; consider keeping track of HCP attendees and incorporating limits on the number of times that an HCP can attend the same program. Incorporate other controls associated with attendance at a training or education program.

Has the Company documented the types of HCPs who should attend the program and how they are selected?

Not every HCP is required to attend all educational or technical training programs. Companies should consider establishing clear criteria for HCP attendees, including specialty types or training needs.

Consider the following questions:

- ❑ What is the primary audience for the training or education program?
- ❑ Who identifies and selects the attendees for the program?
- ❑ Who is responsible for inviting attendees to the program?

Does the Company keep track on HCP attendees and/or limit the number of programs that an HCP can attend in a given period of time?

There may be a legitimate need or reason for an HCP to attend a training or education program more than once. For example, for technical training, an HCP may require attending the same program a few times in order to demonstrate dexterity and competence with respect to a specific procedure. In these instances, consider documenting how the Company measures an HCP's skill pre- and post-program, the complexity of the type of procedure at issue and whether it might merit multiple training sessions, and whether a skills assessment or other documentation should be required in order to attend repeat training.

For some programs, on the other hand, an HCP may not require attending the same program multiple times. In these instances, Companies can document steps taken to ensure that one session is sufficient – for example, making enduring materials available or access to a recording to allow an HCP to refresh knowledge on demand.

Companies should also be mindful of the need to track data on HCP attendees of training and education programs in the event that any items of value are provided that require disclosure under any applicable transparency laws (*e.g.*, the Sunshine Act).

Companies should also be mindful that some in-person training programs may require an HCP's full attendance during all portions of the agenda.

Are sales personnel permitted to attend the program?

Companies should be mindful that the extent and scope of sales personnel attendance at a training or educational program might detract from the legitimate purpose of the event.

Consider the following questions:

- ❑ What is their purpose or role in attending the program? (For example, serving as faculty for an in-service? Require training? Setting up program equipment?)
- ❑ To the extent sales personnel are permitted to attend the program, what instructions are they given regarding their participation?
- ❑ Is the primary focus of the program education and training or does the program allow significant one-on-one time with sales personnel, networking with referral sources, or other promotional opportunities?

Are HCPs' guests, family, or spouses permitted to attend the program?

Guests, family, or spouses of HCPs should not attend a training or educational program unless they have a legitimate need to attend (for example, they are also an HCP that meets the qualifications for attendance that the Company has established).

Do HCPs receive any compensation to attend the program?

HCPs should not be compensated to attend an education or training program. Depending upon the type of program and the controls in place, an HCP may receive modest meals or refreshments, educational items, and travel and lodging to attend the program.

Answer should be "yes"

Answer can be "yes" or "no" – depends on program

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What’s Next

- **Addressing Investor Members**
  - Encourage Investor-company members to confirm that they support the cornerstone values of the Code and expect their health care portfolio companies to abide by the Code
- **Enhancing Preamble**
  - Additional language to include broader Patient Access issues
- **Benchmarking & Surveys**
  - Compliance Department Size & Scope
  - HCP Meals
  - Medical Education Programs

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Learnings for Coalition Members

- **Value of Post-Pandemic Reflection**
  - Is the Code tailored for hybrid and virtual interactions?
- **Transformational Innovation and New Biz Models**
  - Does the Code address? MedTech = Solutions Partner (not Vendor)
- **Elevated Association Support**
  - The need is greater than ever for MedTech associations to provide support, tools, trainings, and benchmarking to advance aligned implementation by all member companies

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Coffee Break

Inter-American Coalition for Business Ethics in the Medical Technology Sector
Los Angeles | 6 June 2022

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Presentation and Q&A on Global Distributor Toolkit Implementation in the Americas and Strategy Discussion on Implementation Next Steps

Sujata Dayal
Vice President & Global Chief Compliance Officer,
Medline Industries

Chair, AdvaMed Chief Compliance Officer's Committee

GLOBAL DISTRIBUTOR COMPLIANCE TOOLKIT

PRESENTED BY SUJATA DAYAL, CHAIR, CCO COMMITTEE

THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

6 JUNE 2022

ETHICAL THIRD PARTY RELATIONSHIPS

Third-party sales and marketing intermediaries (e.g., distributors) contract with medical device researchers and manufacturers to support their commercial activities.

Interactions between distributors and healthcare professionals ("HCPs") or government officials ("GOs") remains a high-risk area for unethical conduct in the supply chain across the Americas, potentially harming patients by:

- Encouraging HCPs/GOs to procure and prescribe unnecessary, inaccurate or faulty products;
- Increasing costs and lowering quality of care to finance bribery and kick-backs;
- Curbing trust between patients and healthcare professionals; and
- Disrupting vital supply chains and spurring retaliatory government action that unsettles trade flows while discouraging future investment.

Ethical third party intermediary relationships is especially critical amidst the COVID-19 pandemic.

THE SOLUTION: DISTRIBUTOR EMPOWERMENT

Empower medical technology distributors of any size with the tools and resources needed to independently build and implement effective compliance programs.

- Digital tool to increase transparency in the medical supply chain;
- Standardized set of free compliance tools and resources tailored to medtech distributors;
- Simple to understand and easy to translate;
- Organized with progressive complexity to facilitate swift implementation;
- Hosted on a user-friendly, needs-focused, and widely available digital platform with downloadable assets in multiple languages for online and offline use; and
- Produced by the private sector, welcome by governments, and implemented through trade association-led, multi-stakeholder training programs and initiatives.

ADVAMED DISTRIBUTORS WORKING GROUP

From 2019-2021, AdvaMed led a team of member compliance officers, graphic designers, web developers and translators to construct Global Distributor Compliance Toolkit.

Members:

- Boston Scientific
- Cardinal Health
- Edwards Lifesciences
- Elekta
- Johnson & Johnson
- Medtronic
- Siemens
- Smith & Nephew
- Stryker
- Wright Medical

Countries:

- Australia
- **Colombia**
- Germany
- **Mexico**
- Singapore
- Spain
- Switzerland
- **United States**

GLOBAL DISTRIBUTOR COMPLIANCE TOOLKIT

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KIT DE FERRAMENTAS DE CONFORMIDADE PARA DISTRIBUIDORES GLOBAIS

Reconhecendo funcionários do governo

Exemplos de funcionários do governo

Um funcionário do governo pode ter vários tipos e classificações, incluindo, entre outros:

- Um médico que trabalha em um hospital público ou leciona em uma universidade pública
- O engenheiro técnico de um hospital público
- Médicos, enfermeiras, farmacêuticos ou funcionários contratados empregados por um hospital pertencente ou controlado pelo governo
- O funcionário do departamento de compras de um hospital público
- Qualquer candidato do governo, eleito, nomeado ou funcionário de carreira
- Um funcionário do Ministério da Saúde

[insert company / event]

GLOBAL DISTRIBUTOR COMPLIANCE TOOLKIT

Preventing Bribery & Corruption

Product Training: Part 2

- You are hosting a Product Training Meeting on an established product.
- An important key opinion leader will be leading the course. This is the first time he will deliver training on this product.
- The majority of the Health Care Professionals (HCPs) attending the meeting live 2-hours or less away from the event.
- The sales representative for each HCP participant wants to attend the meeting. This would make the ratio of sales representatives to participants about 1:5 (one sales rep to five HCPs).
- The marketing manager for the product wants to attend to evaluate the key opinion leader training ability.

How many sales and marketing people should attend the meeting?

Commercial personnel may attend product training meetings when participating in the educational and training experience as a co-learner with the HCP to assist in the teaching and training activity.

Sales personnel who are customarily present in the surgical or operating room environment may need to participate to understand the instructions given to HCPs concerning the proper use of the device.

Your company must ensure the attendance of sales personnel does not detract from or interfere with the educational experience of the HCP. It is important to ensure that training meetings do not look like sales/promotional meetings. A large number of commercial employees at a training can lead to this appearance. **It is important to assess if the commercial personnel who want to attend have a legitimate need or business reason to do so and if they can achieve their goal at another event/venue/meeting.**

HERRAMIENTAS DE CUMPLIMIENTO NORMATIVO PARA DISTRIBUIDORES GLOBALES

Áreas clave de cumplimiento global

- Reconocimiento de funcionarios públicos
- Identificación de conflictos de intereses
- Prevención del soborno y la corrupción
- Llevar buenos libros y registros
- Interacción con profesionales de la salud y funcionarios públicos
- Informar una inquietud

HERRAMIENTAS **DE CUMPLIMIENTO NORMATIVO PARA DISTRIBUIDORES GLOBALES**

PREVENCIÓN DEL SOBORNO Y LA CORRUPCIÓN

El soborno y la corrupción son temas globales y los gobiernos de todo el mundo los toman muy en serio. El soborno de funcionarios públicos es un delito conforme al derecho local e internacional; por ejemplo, la Ley contra el Soborno del R.U. y la Ley de Prácticas Corruptas en el Extranjero de EE. UU., entre otras.

La corrupción no se limita al soborno. Las leyes mundiales y locales contra la corrupción prohíben actividades como la malversación de fondos, la extorsión y la contratación o el ascenso de determinadas personas con fines de lucro privado o político.

Se ha determinado que las empresas mundiales son responsables de las medidas inapropiadas adoptadas por sus distribuidores en todo el mundo para obtener una ventaja comercial indebida. Por ejemplo, en 2012 una empresa global de dispositivos médicos fue multada con 22 millones de dólares por las autoridades estadounidenses por pagar sobornos a través de distribuidores en Europa para ganar negocios.

Usted es responsable de acatar **TODAS** las leyes contra el soborno y la corrupción locales e internacionales aplicables.

El incumplimiento de las leyes contra el soborno y la corrupción puede dar lugar a severas sanciones civiles y penales, así como a daños en su reputación como individuo, la de su empresa y sus socios comerciales.

PONER ESTO EN PRÁCTICA...

- Está participando en una licitación en nombre de un fabricante de dispositivos médicos. La funcionaria de compras del hospital le dice que seleccionará a su compañía para ganar la licitación si le da un empleo en su empresa a su cónyuge.
- Usted está esperando un envío de productos de dispositivos médicos. Un funcionario de aduanas del gobierno le dice que acelerará el papeleo de la importación por un arancel adicional de 50 dólares.

¿QUÉ DEBE HACER?

En ambos escenarios, usted debe rechazar la solicitud y denunciar el pedido de inmediato. No se debe efectuar ningún pago para agilizar los servicios gubernamentales rutinarios, ni tampoco se deben hacer pagos no autorizados a funcionarios públicos en relación con sus obligaciones.

Es importante señalar que el soborno adopta muchas formas; no siempre es de naturaleza financiera. Contratar a un pariente o amigo de un responsable a cambio de un favor es también una forma de soborno. Nunca se debe aceptar o estar de acuerdo con un favor a cambio de negocios de la empresa, incluso si se considera «normal» o «habitual» en el país donde realiza sus negocios.

Nunca se lo penalizará por presentar una denuncia de buena fe de una conducta inapropiada, y debe reportar este comportamiento a su empleador en forma inmediata.

FORMULÁRIO DE SOLICITAÇÃO DE SUBSÍDIO/DOAÇÃO

KIT DE FERRAMENTAS **DE CONFORMIDADE PARA DISTRIBUIDORES GLOBAIS**

SOLICITAR FORMULÁRIO	
Escolha o tipo de subsídio ou doação (consulte a lista em anexo para obter mais detalhes)	☐ Contribuição de caridade ☐ Pesquisa ☐ Educação em saúde/educação pública ☐ Equipamentos médicos, suprimentos, etc. ☐ Bolsa/subsídio acadêmico ☐ Outro_____
Forneça detalhes sobre o financiamento, equipamento ou serviços a serem fornecidos	
ORGANIZAÇÃO SOLICITANTE	
Nome da organização	
Pessoa de contato	
Endereço	
Código postal	
País	
Fone/fax	
E-mail	
Forneça uma descrição do propósito da caridade, educacional ou científico da organização	
Indique a finalidade específica da bolsa ou doação solicitados	☐ **Educação:** descreva o tipo de evento educacional, data, local, nome e anexe quaisquer brochuras ou informações impressas disponíveis; identificar o público-alvo pretendido: ☐ **Subsídio acadêmico:** forneça as datas, detalhes e localização do programa, discriminação de custos e forneça quaisquer materiais disponíveis, incluindo formulários de inscrição: ☐ **Pesquisa:** forneça uma descrição dos objetivos do estudo, resultados e outros detalhes disponíveis: ☐ **Equipamento:** forneça uma descrição do equipamento a ser adquirido, estimativa de custo, fornecedor, uso pretendido e local de uso: **Doações para caridade:**
PROCESSO DE APROVAÇÃO	
Envie este formulário preenchido para	
DOCUMENTAÇÃO ADICIONAL	
Inclua todas as cartas de solicitação recebidas da organização solicitante.	
CERTIFICAÇÃO	
Confirmo que as informações fornecidas são verdadeiras e completas, de acordo com o meu conhecimento, após investigação razoável. Certifico ainda que a bolsa ou doação não está sendo oferecido ou fornecido como uma concessão de preço, recompensa a clientes favorecidos ou incentivo para recomendar, prescrever ou comprar produtos ou serviços da Empresa, e não está vinculado de forma alguma ao uso passado, presente ou futuro dos Produtos ou serviços da empresa.	
Assinatura:	Data:
APROVADOR (CEO/CFO/CCO/ETC.)	
Eu aprovo o subsídio/doação fornecido:	
Assinatura:	Data:

[insert company / event]

GLOBAL DISTRIBUTOR COMPLIANCE TOOLKIT

NOTIFICATION ON USE OF SUB-DISTRIBUTORS

The undersigned, representative of "Your Company Name", confirms on behalf of the Company that in accordance with the Distribution Agreement executed between the Company and [Insert company name] effective [Date] (the "Agreement") the below sub-distributors are proposed by the Company to provide activities under the Agreement.

Information of the Sub-Distributor(s):

Full Name:

Business Address:

Business Registration Number:

Contact Person:

Activities to be Provided:

Rationale of Appointment:

_____
Name

_____
Signed
For and on behalf of [Insert company name]

_____
Date

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TO VISIT THE TOOLKIT VISIT:

https://www.advamed.org/issues/ethics-compliance/global-distributor-compliance-toolkit

OR

https://www.interamericancoalition-medtech.org/ethics/resources/distributors-portal/

STRATEGY DISCUSSION QUESTIONS

1) **How can the Global Distributors Compliance Toolkit support your organization and its members, employees, and/or distributors?**

2) **Is your organization currently or planning to undertake any activities where the Toolkit could serve as a helpful resource?**

3) **What more should the Inter-American Coalition do to foster ethical third-party intermediary relationships across the region? How can the Coalition support uptake of the Toolkit?**

INTER-AMERICAN COALITION FOR BUSINESS ETHICS
MEDICAL TECHNOLOGY SECTOR

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Presentation on Brazil Public Procurement Law (Law n. 14.133/21) and Strategy Discussion on Driving Integrity through Public Procurement

Carlos Gouvêa
Executive President, Câmara Brasileira de Diagnóstico Laboratorial (CBDL) and Institutional Relations, Instituto Ética Saúde (IES)

Lorena Brito da Justa Croitor
Federal Auditor of Finance and Control, Coordinator of Audit in the Health Area, Comptroller General of the Union, Brazil

Bruno Boldrin Bezerra
Executive Director, Associação Brasileira de Importadores e Distribuidores de Produtos para Saúde (ABRAIDI)

Carolina Palhares
Director of Integrity, Ministry of Health, Brazil
(Virtual)

Presentation on Brazil Public Procurement Law (Law n. 14.133/21)

Inter-American Coalitions for Business Ethics and Regulatory Convergence in the Medical Technology Sector

5-7 June 2022 | Los Angeles, California, United States

Evolução da Legislação sobre licitações e contratos no Brasil (Evolution of Brazilian Federal Procurement Law)

Lei 8.666/1993

Lei geral de licitações

Lei 10.520/2002

Instituiu o Pregão presencial ou eletrônico como modalidade de compra

Lei 12.462/2011

Instituiu o regime diferenciado de contratações públicas para obras de engenharia

Lei 14217/2021

Lei 14124/2021

Leis específicas para o enfrentamento da pandemia de COVID

Lei 14133/2021

Lei geral de licitações e contratos

Conceitos trazidos pela Lei 14.133 (Concepts addressed in the Law)

Inovação

Gestão de riscos

Transparência

Integridade

Inovação
(Innovation)

Nova modalidade: Diálogo competitivo

Objetos que envolvam inovação tecnológica ou técnica e outras condições expressas na Lei

Fase de diálogo com participantes pré-selecionados

→

Fase competitiva

Gestão de riscos (Risk Management)

Elaboração de matriz de alocação de riscos:

- Cláusula contratual definidora de riscos e de responsabilidades entre as partes e caracterizadora do equilíbrio econômico-financeiro inicial do contrato em relação a eventos supervenientes

Obrigatória para contratações de grande vulto

(acima de R$ 216 milhões / aprox. US$ 45 milhões)

Transparência (Transparency)

Criação do Portal Nacional de Contratações Públicas:

- Lançado oficialmente em agosto/2021
- Divulgação centralizada e obrigatória dos dados relativos ao processo de aquisição e aos contratos firmados

PORTAL NACIONAL DE CONTRATAÇÕES PÚBLICAS

Integridade (Integrity)

Implantação de Programa de Integridade pelas empresas:

Obrigatória	• Em até 6 meses após a celebração de contrato de obras, serviços e fornecimentos considerados de grande vulto (acima de R$ 216 milhões /aprox. US$ 45 milhões)
Outras situações	• Como um dos critérios de desempate • Na aplicação de sanções administrativas • Como condição de reabilitação após a aplicação de sanções

Período de transição (Transition period)

Data da publicação

01 de abril de 2021

01 de abril de 2023

Revogação imediata:
Arts. 89 a 108 da Lei nº 8.666/1993
(seção de crimes e penas)

Revogação após decorridos 2 anos da publicação:
Lei nº 8.666/1993, Lei nº 10.520/2002, e os arts. 1º a 47-A da Lei nº 12.462/2011

Processo de implementação da Lei (Implementation process)

Integração dos Entes Federativos ao Portal Nacional de Contratações Públicas

Regulamentação de temas específicos

Muito obrigada!

Maiores informações e contatos:

www.gov.br/cgu

sfc.cgsau@cgu.gov.br

lorena.croitor@cgu.gov.br

CONTROLADORIA-GERAL DA UNIÃO

PÁTRIA AMADA BRASIL GOVERNO FEDERAL

Inter-American Coalitions for Business Ethics and Regulatory Convergence in the Medical Technology Sector

Driving Integrity Through Public Procurement

Carolina Palhares Lima
Integrity Department
Ministry of Health

INTEGRITY DEPARTMENT

PROCUREMENT ANALYSIS

FRAUD INVESTIGATION

INTEGRITY

BEST PRACTICES IN PUBLIC PROCUREMENT

MINISTÉRIO DA SAÚDE

2022 2023

PLANO DE INTEGRIDADE DO MINISTÉRIO DA SAÚDE

DISTRIBUIÇÃO GRATUITA
VENDA PROIBIDA

SEMEANDO INTEGRIDADE

Brasília – DF
2022

www.gov.br/saude/dinteg

TRANSPARENCY

Transparency Index

Transparency in public procurement

GOVERNANCE PROJECT FOR MEDICINES AND VACCINES PROCUREMENT

WHY?

HOW?

Developing governance and managing risk in public procurement as a way to ensure that population can access medicines and vaccines.

GOVERNANCE PROJECT FOR MEDICINES AND VACCINES PROCUREMENT

RISK MANAGEMENT

COSO

ISO 31000

RISK MAP			
Identification of risk events			
RISK EVENTS	CAUSES	EFFECTS/ CONSEQUENCES	RISK TREATMENT MEASURES
Event 1	C 1	E/C 1	R1
	C 2	E/C 2	R2
	C n	E/C n	R3
Event 2	C 1	E/C 1	R4
	C 2	E/C 2	R5
	C n	E/C n	R6
Event 3	C 1	E/C 1	R7
	C 2	E/C 2	R8
	C n	E/C n	R9

DIAGNOSIS

MEDICINES AND VACCINES

AMOUNT

STOCK

XX units
Stock 1

YY units
Stock 2

ZZ units
Stock 3

SUPPLIERS

RESULTS

Governance

Regulation

Rules and guidelines

Documents

Professional Training

Communication

RESULTS

Procedural instruction

Managing conflict of interest

Procurement analysis

Fraud investigation

Sanctions

Access

THANK YOU!

Carolina Palhares Lima
MINISTRY OF HEALTH

www.gov.br/saude/dinteg
dinteg@saude.gov.br

INSTITUTO ÉTICASAÚDE

ETHICS AND INTEGRITY:

SUSTAINABLE HEALTHCARE THAT CREATES VALUE

Who we are

The Institute Ética Saúde (IES) is a nonprofit civil society organization that brings together companies and institutions in a voluntary endeavor to create rules for preventing bribery and corruption in the health sector.

The Institute seeks to ensure the sustainability of the health system by encouraging ethical conduct by the different stakeholders in an environment of fair and transparent competition.

The IES is an important tool for mobilizing and transforming the healthcare market in Brazil.

Who we are

Change inductor for the consolidation of the culture of Ethics and Transparency in the Healthcare Sector

Created in June, 2015

- ✓ **Self-regulation**
- ✓ **Governance**
- ✓ **Bylaws** click here
- ✓ **Normative Instructions** click here
- ✓ **Prevention and Control**

Mission

Disseminate and consolidate the culture of ethics and transparency in health to ensure the sector sustainability and patient safety

Overall Goal

Promote an ethical and responsible business culture, engaging social participation by agents in the health sector, aiming to ensure fair, transparent and competitive environments, thereby contributing to the development of a more ethical society.

Specific Goals

- ✓ Increase awareness of the costs of opportunism and lack of transparency
- ✓ Combat offers of undue advantages to induce demand for treatments and procedures
- ✓ Encourage transparent and consistent business transactions by agents in the health sector

Values

Ethic

Integrity

Awareness and Education

Transparency

Legality

Governance

- HEALTH SERVICES
- PAYMENT SOURCES
- HEALTH PROFESSIONALS
- MANUFACTURERS
- DISTRIBUTORS

Advisory Board | 28 members

Board of Ethics

Dr. Antonio Fonseca
Ministério Público Federal (MPF)

Prof. Dr. Celso Grisi
da Universidade de São Paulo (USP)

Dr. Edson Luiz Vismona
Instituto Brasileiro de Ética Concorrencial (ETCO)

Prof. Dr. Mário Aquino Alves
Fundação Getúlio Vargas (FGV)

Paulo Silva
Conselheiro Fiscal em Empresas de grande porte

175 MEMBERS

DISTRIBUTORS AND IMPORTERS| 153 companies

MANUFACTURERS| 14

LABORATORYS| 02

HOSPITALS AND O.S.S.| 07

Cooperation Agreements

MP AMPASA

TCU TRIBUNAL DE CONTAS DA UNIÃO

ANVISA

CADE Conselho Administrativo de Defesa Econômica

CONTROLADORIA-GERAL DA UNIÃO

PÁTRIA AMADA BRASIL GOVERNO FEDERAL

INSTITUTO NÃO ACEITO CORRUPÇÃO

FGV EAESP CENTRO DE ESTUDOS EM ÉTICA, TRANSPARÊNCIA, INTEGRIDADE E COMPLIANCE

Observatório® SOCIAL DO BRASIL

Abramed ASSOCIAÇÃO BRASILEIRA DE MEDICINA DIAGNÓSTICA

In progress

ANS Agência Nacional de Saúde Suplementar

CAPITALISMO CONSCIENTE® BRASIL

UNODC United Nations Office on Drugs and Crime

Institutional and Government Relations

Government Relations| Advocacy in Congress

Bills of Law

- ✓ 221/2015
- ✓ 407/2015
- ✓ 434/2015
- ✓ 445/2015
- ✓ 973/2015
- ✓ 2425/2015
- ✓ 438/2020

- ✓ Medical Corruption
- ✓ Medical Fraud
- ✓ Improper reuse of implantable medical device
- ✓ Fraud in the stipulation of the value of the implantable medical device
- ✓ Therapeutic fraud sponsorship

WHAT WE DO

Awareness and Education

✓ *Events | Webinars*

✓ *Education Programs | Research and Studies*

FGV EAESP
CENTRO DE ESTUDOS EM ÉTICA, TRANSPARÊNCIA, INTEGRIDADE E COMPLIANCE

Compliance na Formação do Profissional da Saúde

Conexão Fehosp

WHAT WE DO

Awareness and Education

- ✓ *campaigns*

- ✓ *Articles | News | Interviews*

WHAT WE DO

REGULATION AND MONITORING

Assessoria para Aquisição de Produtos para Saúde
COVID-19

PLANTÃO DE DÚVIDAS
COVID-19
IES

Questionário de Autoavaliação

Instruções Normativas

LGPD

GUIA – Ministérios Públicos

epihc
ETHICAL PRINCIPLES IN HEALTH CARE™

WHAT WE DO

VALUE OF ETHICS

Qualification Program

Click here

WHAT WE DO

BRAZILIAN CONSENSUS FRAMEWORK

Click here

FGV EAESP

CENTRO DE ESTUDOS EM ÉTICA, TRANSPARÊNCIA, INTEGRIDADE E COMPLIANCE

INSTITUTO ÉTICA SAÚDE

Corruption Perception Index in the Health Sector

PROJECT

- Identifying and Mapping Corruption Risks in the Health Sector in Brazil

- Assessing the Perception of Corruption in the Health Sector

FGV EAESP
CENTRO DE ESTUDOS EM ÉTICA, TRANSPARÊNCIA, INTEGRIDADE E COMPLIANCE

INSTITUTO ÉTICA SAÚDE

www.eticanaoemoda.org.br

Campaign video

https://www.youtube.com/watch?v=u6GA3dx-fIo

Administrative Contracts and Tender Law

Federal Law # 14.133

Administrative Contracts and Tender Law

- Issued on April 1st 2021 = Federal Law # 14.133
  - 2 years to co-exist with the previous tender laws

- Objectives
  - Focus on allow more transparency in the procurement processes
  - Restrain corruption in public contracts
  - Focus on the final result, setting standards based on good practices (like eletronic bidding process)

- Scope
  - Federal Government, States, Municipalities
  - Direct Administration, Autarchies, Foundations

- 5 Tenders modalities
  - “Concorrência”, “Concurso”, “Leilão”, “Pregão” and Diálogo Competitivo”

Administrative Contracts and Tender Law

- Judgment Criteria
  - Lowest price
  - Higher discount
  - Best technique or artistic content
  - Technique and price
  - Highest bid
  - Highest economic return

- National Portal of Public Procurement (PNCP)
  - Data base with all information related to public procurement processes and contracts of all government levels.
  - Unified public system
  - It will be under the responsibility of a Managing Committee of the National Network of Public Procurement

Administrative Contracts and Tender Law

- Phases
  - Preparatory
  - Publicity of the Tender RFP
  - Presentation of proposals and bidding process
  - Assessment
  - Habilitation
  - Appeal
  - Homologation / Ratification

- Crimes in tenders
  - Penalities foreseen (4 to 8 years in prison + fines)

- Integrity Programs
  - Mandatory for those companies that participate in tenders valued above BRL 200 MM (=USD 40 MM) per year.

INSTITUTO ÉTICASAÚDE

Thank you !

Carlos Gouvêa

eticasaude@eticasaude.org.br
www.eticasaude.org.br

Panel Questions

1. ***Are there any questions on Brazil Public Procurement Law (Law n.14.133.21)?***
2. ***What are the opportunities/challenges related to advancing integrity in public procurement laws in other countries of the region?***
3. ***Should the Coalition prioritize this area for further action? If so, how?***

INTER-AMERICAN COALITION FOR BUSINESS ETHICS
MEDICAL TECHNOLOGY SECTOR

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Status Updates by Coalition Members (3 Minutes)

Inter-American Coalition for Business Ethics in the Medical Technology Sector

Los Angeles | 6 June 2022

COALITION PRINCIPAL MEMBERS	
CADIEM (Argentina)	CAPRODI (Argentina)
ABIIS (Brazil)	IES (Brazil)
ABIMO (Brazil)	ABIMED (Brazil)
ABRAIDI (Brazil)	CBDL (Brazil)
MedTech Canada	ANDI-CDMIS (Colombia)
APIS (Chile)	ADIMECH (Chile)
SCDM (Chile)	ASEDIM (Ecuador)
AMID (Mexico)	ASEMED (Mexico)
CANIFARMA-MD Committee (Mexico)	COMSALUD-CCL (Peru)
AdvaMed (United States)	AVEDEM (Venezuela)
ALDIMED (Regional)	ALADDIV (Regional)

INTER-AMERICAN COALITION FOR BUSINESS ETHICS
MEDICAL TECHNOLOGY SECTOR

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector

Los Angeles | 6 June 2022

Welcome Members

COALICIÓN INTERAMERICANA PARA LA CONVERGENCIA REGULATORIA
SECTOR DE TECNOLOGÍA MÉDICA

COALIZÃO INTERAMERICANA PARA CONVERGÊNCIA REGULATÓRIA
SETOR DE TECNOLOGIA MÉDICA

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR