

# Global Business Conduct Standards on Interactions with Health Care Professionals

## **The Standards**

# Contents

|    |  |  |
|----|--|--|
| 3  | Introduction   |  |
| 3  | Accountability   |  |
| 3  | Assessment   |  |
| 3  | Compliance Leadership  |  |
| 3  | Effective Lines of Communication                                     |  |
| 3  | Investigation and Remediation  |  |
| 3  | Training   |  |
| 3  | Written Policies   |  |
| 4  | Commitment to Compliance   |  |
| 4  | What's at Stake?   |  |
| 4  | Who Must Follow the Standards?                                       |  |
| 4  | How to Seek Advice?  |  |
| 4  | What happens When You Contact the Hotline?                           |  |
| 4  | Compliance Leadership Responsibilities                               |  |
| 5  | Employee Responsibilities  |  |
| 5  | The Four Compliance Questions  |  |
| 5  | How to Seek Advice?  |  |
| 5  | Can I Remain Anonymous?  |  |
| 6  | Manager Responsibilities   |  |
| 6  | Internal Investigations  |  |
| 7  | The Standards  |  |
| 7  | Waivers and Amendments   |  |
| 7  | Report Issues or Ask Questions                                       |  |
| 8  | Medical Device Laws and Regulatory Requirements                      |  |
| 8  | Adherence to Product Labeling  |  |
| 8  | Sales and Marketing Practices  |  |
| 8  | Responding to Unsolicited Request for Off-Label Medical Information  |  |
| 8  | Providing Technical Support During Patient Procedures                |  |
| 9  | Product Training   |  |
| 9  | Interactions with HCPs   |  |
| 9  | Use and Protection of Confidential Personal Health Information (PHI) |  |
| 9  | Health Insurance Portability and Accountability Act (HIPAA)          |  |
| 9  | Business Associate Agreements (BAAs)                                 |  |
| 10 | Hospitality  |  |
| 10 | Educational Items  |  |
| 10 | ELGX-Controlled Speaker Programs (CSP)                               |  |
| 10 | Restricted Educational Grants  |  |
| 10 | Written Arrangements with HCPs                                       |  |
| 11 | Bribery and Corruption   |  |
| 12 | Where to Find More Information?                                      |  |
| 12 | Notes  |  |

## Introduction

Endologix recognizes Health Care Professionals (HCPs) are ethical partners in our ability to fulfill our purpose. We collaborate with HCPs to create new products and therapies and improve existing products. We sponsor scientific research conducted by HCPs to gather clinical evidence related to our products. We are committed to adhering to applicable laws regarding physician-initiated use of our products and respect an HCP's right to make independent medical decisions when treating patients. Our marketing, medical education, and promotional activities are consistent with these commitments, and we comply with governing laws regarding appropriate promotion of our products.

In no instance will Endologix offer or provide payment to an HCP as an unlawful inducement to purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe an Endologix product or service.

All of these interactions are for the ultimate benefit of patients. To meet our commitment to high ethical standards, we have a Comprehensive Compliance Program (Compliance Program) designed to detect and prevent behaviors that could harm Endologix and the people we serve. We recognize that compliance is a dynamic concept and regularly review and update the Compliance Program to improve it and ensure it is effective. The Compliance Program is based on recognized government guidelines and industry standards for effective compliance programs:

### Accountability

We require all employees to adhere to the Standards and company policies and procedures as a condition of their employment. We support ethical behavior, evaluating it as part of annual performance reviews, promptly investigating reports of misconduct and taking prompt disciplinary action against those who violate our policies and Standards.

### Assessment

We perform monitoring and auditing of the Compliance Program to evaluate its effectiveness.

## Effective Lines of Communication

We promote an environment where employees can raise questions and concerns and ask for clarity without fear of retaliation. We offer Communication Channels for employees to report violations, including an Open Door process and a confidential Hotline.

## Investigation and Remediation

Results of investigations, audits and monitoring are communicated according to policies and procedures. When an area for improvement is identified, we take appropriate corrective action.

## Training

We provide appropriate education and training of employees, consultants, distributors, and independent sales representatives to help them meet their ethical and compliance obligations.

## Written Policies

Our commitment to ethics and compliance is set forth in our policies and procedures that help us follow relevant laws, regulations, industry codes, and best practices.



## Commitment to Compliance

Our business activities are conducted in a complex world of laws and regulations. As a company with global presence, such laws and regulations vary from one geographic region to another, and it is the responsibility of our employees to ensure that their business activities comply with laws and regulations relative to their respective location.

The Standards do not provide an exhaustive discussion of the legal and ethical requirements employees must adhere to, but rather are intended to make employees aware of the common issues they may confront from time to time in conducting Endologix business globally. The Compliance Program includes policies or procedures that contain more detailed instructions concerning the issue. Some of these policies and procedures are referenced in the Standards, but employees are responsible for determining when a more specific policy or procedure applies. If you have any doubt as to the lawfulness or reasonableness of any proposed activity you should seek advice from Compliance Leadership before such action is undertaken.

### What's at Stake?

The laws that apply to compliance are far-reaching and overlapping. As a result, single acts of misconduct can raise issues under multiple statutes and jurisdictions. Punishments can be severe, resulting in multi-million-dollar civil penalties and criminal convictions that involve major fines and, in some cases, imprisonment. There are government sanctions that can potentially devastate an entire company. Under U.S. Federal and state laws, all parties who engage in illegal activity may be held accountable. This means that our HCPs, along with Endologix employees, can be prosecuted for violations.

### Who Must Follow the Standards?

The Standards apply globally to all employees and officers of Endologix worldwide, as well as any third-party who is or may be authorized by Endologix to represent or act on behalf of Endologix in engaging HCPs. Employees may include contractors, distributors, agents, and independent sales representatives.

## How to Seek Advice?

You may need advice or assistance in order to resolve an issue. Your manager typically should be the first person you turn to for help. If you are not comfortable discussing an issue with your manager, other resources are available. If you are not comfortable speaking with anyone inside of Endologix, you may contact the toll-free Endologix Hotline at 1.855.271.2822 or via the web portal [www.endologixhotline.ethicspoint.com](http://www.endologixhotline.ethicspoint.com). The Endologix Hotline is an external reporting service operated by an independent company, not Endologix employees; translators are available in five languages upon request.

## What Happens When You Contact the Hotline?

A customized web form that either you or a professional interview specialist completes, documents your question or concern in detail and relays to Endologix for follow-up. You may be asked to check back to provide additional information or answer questions as your concerns are investigated. All questions or concerns shared through the Hotline are handled promptly, appropriately, and discreetly. You may choose to seek advice or report concerns anonymously, if permitted by applicable local law.

## Compliance Leadership Responsibility

Leadership of the department includes partnering with and advising senior management, business and project leaders, and employees on awareness of global ethical and compliance risks related to the objectives and strategic goals of Endologix.

## Employee Responsibilities

As an employee you are expected to understand the Standards and other Endologix policies and procedures, abide by them, and raise any questions or concerns you may have.

You are responsible for reporting wrongdoing should any occur within Endologix. If you know or suspect that a law has been broken or the Standards have been violated, report it promptly to your manager, any member of senior management, Compliance Leadership, a member of the Human Resources department, the Chief Executive Officer, or contact the Endologix Hotline at 1.855.271.2822 or via the web portal [www.endologixhotline.ethicspoint.com](http://www.endologixhotline.ethicspoint.com).

All employees upon hire are required to conduct themselves in an ethical manner by acknowledging they have access to, understand, and agree to abide by the Standards and Endologix policies and procedures. As an employee, you have a responsibility to cooperate in investigations related to compliance matters. Our policies may change from time-to-time, so it is expected each employee is responsible for knowing and complying with the current laws, regulations, the Standards, and other Endologix policies and procedures that govern our work. You are expected to attend regular training sessions. If you fail to comply you risk being disciplined which may include termination. If you break the law, you may also risk being personally liable.

Ethical conduct is part of everyone's job. We do not change our ethics because competitors may behave differently, or our financial goals aren't being met.

## The Four Compliance Questions

There are four questions you may ask yourself if you are approached with a new situation, question, challenge, problem, or temptation while doing your work:

1. Will my action violate any laws or regulations?
2. Will my action violate Endologix policies or procedures or any provisions of the Standards?
3. Will I be proud of my action if seen by my co-workers, family, friends, regulators, or the media?
4. Will my action be honest, fair, and promote the values of Endologix?

## How to Seek Advice?

Always feel free to discuss any situation with your manager. It is your manager's responsibility to help solve problems and it is up to both of you to report suspected violations of Endologix policies and procedures or the Standards to Compliance Leadership or the Endologix Hotline at 1.855.271.2822 or via the web portal [www.endologixhotline.ethicspoint.com](http://www.endologixhotline.ethicspoint.com). We do not permit retaliation of any kind against employees for good faith reports of ethical violations.

In cases where it may not be appropriate or you feel uncomfortable discussing an issue with your manager, you may discuss the situation with other Endologix representatives (including Vice Presidents or executive officers, Compliance Leadership, a member of the Human Resources department, a General Manager, the Chief Executive Officer, or contact the Endologix Hotline at 1.855.271.2822 or via the web portal [www.endologixhotline.ethicspoint.com](http://www.endologixhotline.ethicspoint.com)).

## Can I Remain Anonymous?

If you report an issue or want to ask for clarity regarding a policy, your identity and the information you share will be provided on a "need-to-know" basis with those responsible for resolving the concern. You may remain anonymous, as permitted by applicable local law, but if you identify yourself, we will be able to follow up with you and provide specific feedback.

We prohibit retaliation against anyone who raises an issue or helps address a policy or procedure matter in good faith. Any allegation of reprisal will be investigated, and corrective action taken. It is our policy to protect those who do the right thing.

## Manager Responsibilities

If you supervise others, not only are you expected to understand the Standards and other Endologix policies and procedures, abide by them, and raise any questions or concerns you may have, but you have a responsibility to act and communicate in a manner that is consistent with the Standards.

We rely on you to create a culture of compliance in which your employees understand their responsibilities and feel comfortable raising concerns without fear of retaliation. Encourage ethical conduct by personally leading compliance efforts, taking compliance into consideration when evaluating your employees, and reinforcing the importance of our Compliance policies and the Standards. Help your team understand; results are never more important than conduct.

- Model and encourage ethical behavior, always follow Endologix policies and procedures
- Be proactive in addressing people, policies, and procedures that may pose a compliance risk
- Educate your employees about key compliance issues and make yourself available to answer any questions about what is appropriate and what isn't
- Invite Compliance Leadership to your strategy meetings to provide guidance before any potential violations can occur
- Carefully review expense reports, check requests, and invoices
- Tell your employees what you expect of them and maintain an Open Door Communication Channel for them to share their questions and concerns
- Respond to compliance issues promptly and adequately
- Never investigate matters on your own or hire an outside investigator
- Never respond to concerns in a retaliatory manner or allow retaliation by others

## Internal Investigations

The Compliance and Legal Departments are responsible for administering internal investigations of suspected violations of the Standards and related Compliance policies. We assign investigators, including appropriate personnel within Endologix who may include representatives from Compliance, Legal, Human Resources, Finance, Regulatory, and other functional departments, as well as outside legal counsel who have expertise related to the matter.

We may refer financial matters, when appropriate, to the Audit Committee of the Board of Directors. The investigator will work to determine the facts and recommend corrective action. Whenever possible, the person who raised the concern will receive feedback on the outcome. You are expected to cooperate if called upon regarding any investigation. Do not compromise the integrity of the investigative process, i.e., do not circumvent the policy and process and conduct your own investigation.

We use every reasonable effort to prevent conduct that violates our Standards and to stop any misconduct as soon as it is discovered. Misconduct that may result in discipline includes the following:

- Committing or directing someone else to commit violations of law or the Standards
- Failing to promptly raise a known or suspected violation
- Failing to cooperate in an investigation
- Failing to tell the truth during an investigation
- Retaliating against another employee for reporting a concern

## The Standards

Health Care Professionals (HCPs), encompass individuals, institutions, and other entities that prescribe, recommend, purchase or influence the recommendation or purchase of our products or services. We conduct our business with honesty and integrity and obey laws and regulations in conducting our business with HCPs. Our relationships with HCPs are very important to us. We are firmly committed to comply with laws and regulations governing our interactions with HCPs.

Interactions with an HCP can be anything from a brief product-related discussion between a sales representative and an HCP, to an agreement with an institution on the terms of a restricted educational or research grant. **All interactions with HCPs, no matter how brief or informal, must be conducted in accordance with the Standards, Endologix policies and procedures, laws, regulations, and country/industry specific guidelines.** Under no circumstance may an Endologix employee engage in any conduct that unlawfully induces (or appears to unlawfully induce) an HCP to purchase, lease, recommend, use, or arrange for the purchase, lease, or use of an Endologix product or service.

We may compensate HCPs for providing legitimate services for which a business need has been identified in advance. Endologix pays Fair Market Value compensation, providing such arrangements are made in writing and approved by Compliance Leadership.

Endologix is committed to protecting treatment choices from improper financial inducements. Our Standards, which reflect this commitment, are based on applicable laws and industry codes:

- The Federal Anti-Kickback statute, which prohibits companies from providing cash or other value to HCPs to influence the use or purchase of federally reimbursed products
- The Federal False Claims Act, which prohibits a person from knowingly submitting or causing someone else to submit a fraudulent claim for reimbursement to a government-funded health care program. This law may intersect with the Anti-Kickback statutes when product orders are placed, as a result of improper inducements, and later reimbursed by a federally funded health care program.

## Waivers and Amendments

We will waive application of the policies set forth in our Standards only where circumstances warrant granting a waiver. Waivers for directors and executive officers may be made only by the Board of Directors or a designated committee and must be promptly disclosed as required by law or regulation.

## Report Issues or Ask Questions

Employees have a duty to abide by the Standards, Endologix policies and procedures, laws, regulations, and country/industry specific guidelines and to promptly report all known or suspected instances of non-compliance through our Communication Channels. The failure to report known or suspected information may subject an individual to disciplinary action, up to and including possible terminations. There are basically two Communication Channels available for reporting:

1. Notify your direct manager, a member of senior management, Compliance Leadership, any member of the Human Resource department, or the Chief Executive Officer via the Open Door Communication Channel, or
2. Contact the Endologix Hotline a 1.855.271.2822 or via the web portal [www.endologixhotline.ethicspoint.com](http://www.endologixhotline.ethicspoint.com).

## Medical Device Laws and Regulatory Requirements

*We comply with global medical device laws and respect our regulatory requirements.* Our products are heavily regulated by government agencies, health ministries, and other regulatory authorities around the world. Regulatory requirements include marketing approvals, clinical study parameters, good manufacturing practices, design controls, and labeling controls among others.

Although HCPs can lawfully prescribe or use products for unapproved (or off-label) indications, Endologix cannot promote products for off-label indications and are restricted in how we communicate with HCPs about these issues. You have a responsibility to understand and comply with these requirements and to contact the Regulatory, Compliance, or Legal Department or contact the Endologix Hotline at 1.855.271.2822 or via the web portal [www.endologixhotline.ethicspoint.com](http://www.endologixhotline.ethicspoint.com) for guidance or to report any acts that violate laws or regulations.

## Adherence to Product Labeling

*Our business plan is directed toward driving sales growth for approved indications.* Promotional discussions and materials pertaining to approved products are consistent with product labeling requirements. Sales representatives and other commercial field-based staff, including contractors, distributors, independent sales representatives, undergo training on appropriate promotional practices. All labeling, marketing, and HCP facing materials are reviewed and approved by the Marketing Materials Review Committee (MMRC).

## Sales and Marketing Practices

*We market our products honestly and in compliance with all laws and regulations.* We must preserve our reputation as a leading company whose products and services are chosen for their features, innovation, quality, and value. We truthfully describe our products and services and take care to ensure that all promotional material and communications are accurate, fair, balanced, substantiated, and compliant with legal and regulatory standards. Make sure in your marketing practices that you:

- Don't mislead or omit important facts
- Don't promote a product before it is approved
- Don't promote a product for any other use than for which it was approved
- Don't unfairly criticize a competitor's products or services (some countries prohibit all comments about a competitor).

## Responding to Unsolicited Requests for Off-Label Medical Information Uses

*Endologix cannot promote products for unapproved indications; we are restricted in how we communicate with HCPs about these uses.* Unsolicited HCP requests for medical information about off-label uses received by Endologix are reviewed by the Clinical and/or Global Medical Affairs Departments, including the Chief Medical Officer, who ensures any information provided is current, objective, scientifically sound, free of promotional influence, and describes the limitations of the device, making sure the requestor understands what the device can and cannot do.

## Providing Technical Support During Patient Procedures

*HCPs often require that an Endologix representative remain in the clinical setting during patient procedures for the purpose of technical support and answering questions about our products.*

- The representative providing the technical support does not promote the device or any of its features for uses outside the approved product labeling
- If an HCP elects to use a device in a manner not described in the product labeling, the representative limits the discussion of product-related information to the device's labeled IFU, its operating principles, performance specifications, and other technical aspects of the product
- The representative must not touch or make contact with a patient, touch or operate instruments or equipment that delivers or regulates therapy to the patient.



## Product Training

*Endologix has a responsibility to demonstrate the safe and effective use of our product to HCPs (in person and/or virtually):*

- Training must be consistent with approved product IFU labeling
- Training venues include Endologix facilities, independent teaching facilities, such as a hospital, or other appropriate clinical setting
- HCPs who attend training sessions may be reimbursed for reasonable travel and modest lodging and meal costs, however, do not receive compensation for time spent in training.

## Interactions with HCPs

*We interact with HCPs in compliance with laws, regulations, and applicable industry standards. Keep medical decision-making free of improper industry influence – as an employee, you are prohibited from offering or giving anything of value to an HCP in order to induce or influence that person to prescribe, use, purchase, lease or recommend our products or services. In regions of the world where an HCP is also defined as a government employee, extra care must be taken (see section on Bribery and Corruption).*

Patients undergoing medical treatment share the expectation that decisions made on their behalf are guided by objective medical knowledge and experience and are free of improper influence. A growing number of laws, guidelines, and compliance policies have been introduced to help preserve the independence of medical decision-making. They limit and regulate giving or offering anything of value to HCPs to avoid improperly influencing choices. Industry guidelines (such as AdvaMed and MedTech Codes of Ethics) and compliance policies are intended to limit even the appearance of improper influence.

You are responsible for knowing our Compliance policies and procedures regarding promotional activities and interactions with HCPs. Refer to them when you are considering:

- Use of an HCP as a consultant
- Sponsoring medical seminars or educational conferences attended in person or virtually by HCPs

- Requests for restricted educational, research, or fellowship grants
- Scheduling and hosting speaker programs and paying speaker fees
- Sponsoring trips to medical meetings or Endologix facilities.

## Use and Protection of Confidential Patient Health Information (PHI)

*Employees are obligated to comply with laws and rules relating to PHI. This protected information includes individually identifiable information relating to (i) an individual's past, present, or future physical or mental health or condition, (ii) the provision of health care to an individual, or (ii) payment for providing health care to an individual.*

## Health Insurance Portability and Accountability Act (HIPAA)

*The HIPAA Privacy Rule creates national standards to protect an individual medical records and other PHI. HCPs have a duty to safeguard this information which may include paper records and electronically transmitted records. HIPAA provides clear standards for the protection of this information and regulates the way PHI is created, received, transmitted, used and disclosed, and destroyed. Endologix routinely handles PHI, meaning, we must conform to HIPAA rules.*

HIPAA allows Endologix, as a member of the health care team, to share PHI for treatment purposes; employees must use reasonable safeguards when doing so. Treatment communications may occur orally or in writing, by phone, fax, or email. Safeguards may vary depending on the mode of communication used. Please contact Compliance Leadership and/or the Regulatory Department for additional guidance.

## Business Associate Agreements

*Endologix is not a Business Associate. Any request for Endologix to sign a Business Associate Agreement must be forwarded to Compliance Leadership. Under no circumstance should an employee, nor any third-party, consultant or contractor, sign a Business Associate Agreement on behalf of Endologix.*

## Hospitality

*Endologix is expected to adhere to industry standards for providing hospitably, meals, and educational items to HCPs.*

- Sales calls and business meetings are limited to settings conducive to the exchange of scientific, clinical, and educational information
- Endologix may offer occasional and modest meals, as part of business discussion about scientific, clinical, and educational information related to our products
- Recreational or entertainment events with HCPs are prohibited
- Attendance at events by spouse, children or HCP guests is not permitted
- Endologix may offer reasonable, necessary, and pre-approved travel and lodging.

## Educational Items

*Endologix is prohibited from providing items that do not advance treatment, education, or are otherwise not designed primarily for the education of patients or HCPs.*

Items designed primarily for the education of patients or HCPs must not offer value to the HCP outside their professional responsibilities. Examples of appropriate items may include anatomical models, textbooks, or approved written materials that inform patients. Cash or cash-equivalent gifts are prohibited. All educational items require pre-approval from management and Compliance Leadership. Educational items will be monitored, tracked, and reported according to state and Federal requirements.

## ELGX-Controlled Speaker Programs (CPS)

*CPS events, Endologix coordinates, controls the content, and pays an HCP to speak on behalf of Endologix (live or virtually).* Promotion of off-label use is strictly prohibited.

- Speakers present scientific, educational, and promotional and non-promotional information pertaining to our products and services.
- Speakers may be reimbursed for modest meals and reasonable travel and lodging expenses.
- Speakers disclose conflicts of interest, such as financial relationship with Endologix, to institution or association conducting program.
- Requires submission of CPS form packet to include pre-approved presentation to Compliance.

## Restricted Educational Grants

*Endologix may provide restricted educational grants to support legitimate educational activities.* Endologix cannot be involved in the development of content or selection of speakers or authors. All requests for consideration of restricted educational funding must be reviewed by the Grants Review Committee (GRC) and approved by Compliance Leadership.

- Request must come from the entity, must use appropriate request form.
- Funding consistent with nature/scope, source of the grant is disclosed.
- Speaker travel and other expenses are reimbursed by institution or association conducting program, not by Endologix.
- Content is non-promotional, balanced, educationally focused, and developed without input or guidance from Endologix.
- Restricted educational grant terms are clearly documented in a written agreement.
- All grants are monitored, tracked, and reported as required by applicable Federal or state or international laws.

## Written Arrangements with HCPs

*Endologix is permitted to enter into agreements with HCPs who provide legitimate pre-approved services.* Consulting, training and education, clinical research, advisory board participation, product development, and promotional speaking engagements are services that relate to an area of legitimate business need identified on a Business Justification Form (BJF).

- Agreement is clearly documented outlining the HCPs responsibilities, the duration of the arrangement, and the terms of Fair Market Value compensation.
- All written arrangements are managed by Compliance.
- Product-related scientific information is limited to approved IFU labeling or with appropriate disclaimers approved by the MMRC, and all program content undergoes formal copy review.

## Bribery and Corruption

*We do not participate in any corrupt practices, nor do we allow those who work for us or on our behalf to make or receive improper payments, nor do we offer prohibited gifts or entertainment. We do not participate in illegal or unethical behavior in order to sell our products. We keep accurate and transparent business books and records.*

All employees and officers of Endologix worldwide, as well as any third-party who is or may be authorized by Endologix to represent or act on behalf of Endologix must follow the company's Compliance policies, the laws of the country in which they operate, as well as the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act. These laws are serious and far-reaching and companies that violate them risk damage to their reputation and future success, costly lawsuits, substantial fines, and jail time for individuals.

We are committed to securing business based solely on the quality of our products. Regardless of local custom or competitive practices, do not offer, make or authorize, request, agree to receive or receive payment of money or anything of value, including cash, gift cards, gifts, travel expense, entertainment, charitable or political contributions, per diem payments, sponsorships, honoraria, loans or employment offers to:

- Influence the judgment or conduct or to ensure a desired outcome or action
- Win or retain business or influence any act or decision of any governmental official, political party or candidate
- Gain an improper business advantage.

## Where to Find More Information?

### Endologix LLC

External Website: [www.endologix.com](http://www.endologix.com)

Internal Website: [www.pulse.endologix.com/compliance](http://www.pulse.endologix.com/compliance)

Endologix is deeply committed to addressing unmet needs in aortic therapies. Endologix continuously strives to bring groundbreaking and effective solutions to physicians and their patients.

### Department of Justice (DOJ)

Website: [www.justice.gov/guidance](http://www.justice.gov/guidance)

The DOJ, is the U.S. Department of the Attorney General who provides specific compliance guidance.

### U.S. Department of Health and Human Services, Food and Drug Administration

Website: [www.fda.gov](http://www.fda.gov)

A U.S. government agency intended to promote and protect the public health by helping safe and effective products reach the market in a timely way and monitoring products for continued safety after they are in use.

### Office of the Inspector General (OIG)

Website: <https://oig.hhs.gov/compliance>

The OIG is a U.S. Department of Health and Human Services (HHS) Compliance department provides special fraud alerts, advisory bulletins, podcasts, videos, brochures, and papers on providing guidance on compliance with Federal health care program standards.

## Notes

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This information is being provided to you on behalf of Endologix LLC. It is intended to establish Standards of employee conduct and assistance in preventing and detecting criminal or unethical behavior.

**[endologix.com/compliance](https://endologix.com/compliance)**