# Interactions with Healthcare Professionals

**FIELD SALES**
**MANUAL**

aclaris™ THERAPEUTICS

*Effective March 27, 2018*

Integrity
Responsibility
Accountability
Excellence

# Purpose

This policy is a summary of the laws, rules, and regulations governing our interactions with healthcare professionals (HCPs). Each of us has a responsibility to demonstrate a commitment to ethical conduct in all our day-to-day activities. What we do and how we conduct business must reflect our shared commitment to patients and Aclaris' values, including:

| | |
|---|---|
| **INTEGRITY:** | **"Doing the right things, the right way, every time"** |
| **TEAMWORK:** | **"Collaborating in good faith"** |
| **RESPONSIBILITY:** | **"Taking personal responsibility"** |
| **EXCELLENCE:** | **"Being your best"** |

# Scope

It is the responsibility of every Aclaris employee, contractor or agent who engages in the activities described in this policy to be knowledgeable about and comply with the requirements set forth herein. The Company takes violations seriously and failure to comply may result in disciplinary action up to and including termination, so it is important to know the policies and comply accordingly. If you have any questions regarding the rules, practices, and activities described in this policy, please contact the Legal Department or the Compliance Office.

# Definitions

## FOR THE PURPOSES OF THIS POLICY:

| | |
|---|---|
| **Commercial Colleague** | Any member of Sales or Marketing department regardless of level within the Company. |
| **Excluded Specialty** | The specialty of a healthcare professional who is not likely to prescribe a product for its approved use and therefore, healthcare professionals with such a specialty are to be excluded from promotional activities. For example, pediatricians and pediatric dermatologists are specialties excluded for promotional purposes for currently marketed products because these products have not been approved for use with pediatric patients. |
| **Healthcare Professional** | Any member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, recommend, purchase, supply, or administer a pharmaceutical product for human patients, or who may provide healthcare services or may be connected with the provision of health-care services. This means that Aclaris broadly defines HCP to include those persons who directly interact with patients and those who indirectly have a role in patient diagnosis or treatment. Our broad definition of HCPs includes persons such as physicians, pharmacists, medical students, aestheticians, medical assistants, members of drug formulary committees, and health plan administrators; and it also includes entities such as physician practice groups, hospitals, nursing facilities, and clinics. The definition of an HCP may differ in certain contexts, particularly, for example how various states define HCPs. We have designed our systems to take these variances into account where these differences are relevant. |
| **PhRMA Code** | The Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals relating to the interac-tions with healthcare professionals in the marketing of prescription pharmaceutical products. |
| **PRC** | The Promotional Review Committee. |
| **Product Promotion** | Any activity undertaken, organized or sponsored by Aclaris or by a vendor or consultant engaged by Aclaris which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of Aclaris products through all methods of communication, including the internet. |

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CHAPTER 1

# Overview of Relevant Laws and Regulations

***The following list summarizes key aspects of certain laws and regulations particularly influencing the pharmaceutical industry***

## Federal and State Anti-Kickback Laws

Healthcare treatment decisions should not be motivated by personal gain or enrichment. Federal and state anti-kickback laws prohibit improper influences by making it a criminal and/or a civil offense to solicit, pay, or offer anything of value to induce someone to purchase, prescribe, or recommend a product that is reimbursed under federal or state government healthcare programs (e.g., Medicare or Medicaid).

**For example, anti-kickback laws prohibit:**

- Providing a gift to an HCP to influence the prescribing, dispensing, or recommending of pharmaceutical products; or
- Paying for the consulting services of an HCP or other customer at a fee above the reasonable, fair market value for such services.

Some state laws are broader and apply to all items and services including those reimbursed by private insurers.

## State Commercial Bribery Laws

Commercial bribery involves a corrupt dealing (usually a kickback) with the agents or employees of a customer or potential customer to secure an advantage over business competitors. It is a form of corruption which does not necessarily involve government personnel or facilities.

Commercial bribery is usually punishable as a felony under various state's laws and more than 35 states have laws specifically prohibiting commercial bribery. In addition, federal mail and wire fraud statutes can be used to prosecute commercial bribery as a "scheme or artifice to defraud" if the mail or interstate wire facilities are used in the commission of the crime.

## Food, Drug, & Cosmetic Act

The FDCA are laws which grant the Food and Drug Administration (FDA) authority to oversee the safety of food, drugs, and cosmetics, including advertising and promotion of prescription drugs. Any materials (whether in print or electronic form) used to promote our products – including all visual aids, brochures, journal advertising, promotional programs and other sales aids – must include only claims about the product that are:

- consistent with that product's labeling;
- accurate and not misleading;
- and capable of substantiation – meaning appropriately supported by scientific evidence.

## PhRMA Code

The Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Care Professionals (PhRMA Code) is a voluntary code of conduct focused on pharmaceutical companies' interactions with healthcare professionals and the marketing of pharmaceutical products to HCPs. The PhRMA Code requires the ethical promotion of prescription medicines in a way that fosters the pharmaceutical industry's mission of helping patients by discovering, developing and promoting new medicines.

The principles of the PhRMA Code are embedded in Company policies, practices and manuals.

## Prescription Drug Marketing Act

The PDMA prohibits the sale, purchase, or trade of drug samples. It is illegal for any individual (including physicians) to sell or seek reimbursement for a free sample. Individuals who engage in or encourage such conduct are subject to criminal prosecution.

The PDMA also places procedural, record keeping, inventory and audit obligations on prescription drug manufacturers and distributors, and requires specific procedures to deter the diversion of prescription drugs. Refer to the Sample Handbook to learn more about specific requirements relating to the distribution, reconciliation, identification, tracking, auditing and monitoring of samples.

## U.S. Federal Sunshine Act and State Transparency and Disclosure Laws

The Sunshine Act provisions under the Patient Protection and Affordable Care Act require certain disclosures of transfers of value made to physicians and teaching hospitals. State marketing and disclosure laws include restrictions/prohibitions on gifts and meals provided to HCPs; require the disclosure of payments made to HCPs; and require the reporting of certain data. The laws in VT and MN are very restrictive and have national impact.

CHAPTER 2

# Sales Presentations and Product Promotion

Our relationships with HCPs are highly regulated, are intended to benefit patients, and are intended to enhance the practice of medicine. Our interactions with HCPs should be focused on informing them about products and providing scientific and educational information.

This means:

## On-label promotion

- Only information and materials that have been approved for promotional use may be used or distributed relating to product presentations. The Promotional Review Committee (PRC) ensures that promotional materials are consistent with the product's package insert, are truthful and not misleading, and are appropriate for use with the HCP or patient community for which they were created. Federal regulations require that Aclaris file all promotional materials with the FDA at the time of first use with any customer.
- Only discuss approved products and indications.
- Do not discuss new products or indications until approved by PRC.
- Sales presentations must be made to appropriate HCPs. You are required to record all HCP interactions in Veeva CRM and to synchronize Veeva CRM daily.
- Always give a fair and balanced presentation of the benefits and risks of a product.
- Never engage in actual or perceived quid pro quo. Quid pro quo is Latin for "this for that".

**All information disseminated through Aclaris' promotional activities must be:**

1. Consistent with the product's FDA-approved package insert and other labeling, or "on-label;"
2. Fair and balanced with respect to efficacy and safety information;
3. Truthful and not misleading; and
4. Delivered to HCPs who are reasonably likely to prescribe — or to patients/caregivers who are interested in — Aclaris products for their approved use.

## Promotional Materials, Reprints, and Other Items

- Only use Aclaris-approved materials. Never use materials that you or anyone has created or altered in any way.
- All items (such as reprints, textbooks, etc.) provided to HCPs must be educational and PRC- approved.
- Payments in cash or cash equivalents (such as gift cards) must not be provided or offered to HCPs.
- The PhRMA Code prohibits pharmaceutical companies from offering non-educational items such as pens, pads, mugs, etc. to U.S. HCPs or members of their staff, even if the items are practice-related and of minimal value. Therefore, none of these items may be offered or provided to U.S. HCPs.

## Comparative Statements

- All statements must be consistent with the product's package insert, truthful and not misleading.
- You may only make comparative claims that appear in your approved product promotional materials. The FDA considers promotional materials or claims to be false and misleading if they state or suggest that a drug's safety or efficacy is comparable or superior to that of another drug without "substantial evidence" to support such statements or suggestions. "Substantial evidence" in the context of comparative claims generally means two adequate, well-controlled studies comparing the two drugs head-to-head using comparable dosage regimens. In some instances, a single, large, well-controlled study may suffice if first approved by FDA.

## Use of Social Media

- Aclaris may be held accountable for statements and posts of employees or agents, as well as paid or authorized communications. Social media should never be used in a way that violates any Aclaris promotional policies or legal or regulatory obligations.
- You are prohibited from discussing any Aclaris product, business plan, research, strategy or other business-specific details in any social media forum in a way that could be regarded as advertising or promoting a prescription product or otherwise disclosing non-public information.

### Q&A

**My target account has a Facebook page that is frequently visited by patients. Am I permitted to interact with HCPs regarding Aclaris business using any of their social media tools?**

*No. You may only use your Aclaris email account to communicate with HCPs regarding Company business. Furthermore, you may not use any social media tools (e.g., Facebook, Twitter, Instagram, etc.) or any unapproved cloud-sharing/storage applications (e.g., Google Docs, SharePoint, Dropbox, Evernote, etc.) to communicate or share product or business information.*

## Unsolicited Requests for Off-label Information

- You may not initiate discussions with HCPs about off-label information concerning an Aclaris product or a competitor product.
- You must not encourage or solicit HCPs to request off-label information.
- If you receive an unsolicited question or request about off-label information or unapproved clinical data, you must forward the request to Aclaris Medical Information or ask the HCP to directly contact Medical Information **(MedInfo@aclaristx.com)**.

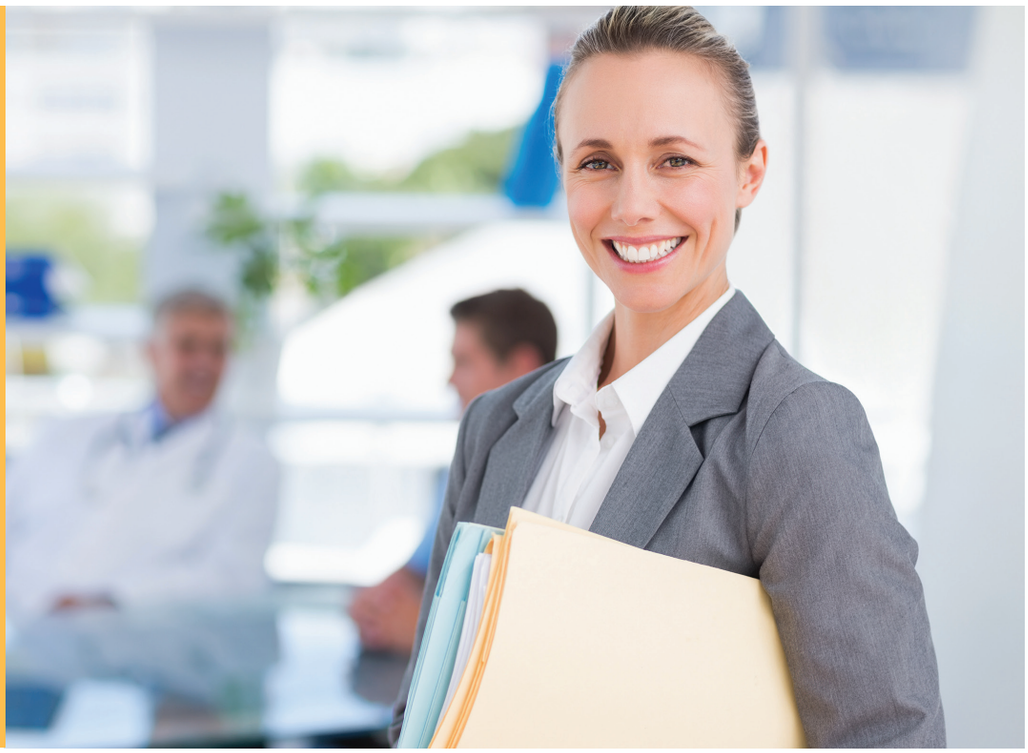
## Adverse Events

- We all have a role to play to help Aclaris deliver on its commitment to improve human health.
- One of your most important responsibilities is to inform the Company of any adverse events (AE) or product quality complaints. We are all required to report to Medical Affairs any AE that may be associated with the use of our products. Immediately or at the latest, within 24 hours of becoming aware of an AE, information must be reported, in accordance with Company policies, by emailing **safety@aclaristx.com** or by calling **833-ACLARIS (833-225- 2747).**

## Use of HCP Prescribing Data

The American Medical Association (AMA) administers a program that allows physicians to opt-out of having their prescriber data released to pharmaceutical sales representatives and requires that opt-out requests be honored within 90 days. In addition, Massachusetts requires that pharmaceutical manufacturers give Massachusetts HCPs the opportunity to request that their prescriber data be withheld from sales representatives and not be used for marketing purposes.

- The Company does not receive prescriber data. However, the Company receives aggregate treatment data and sales information from various sources, which it utilizes to create an estimate of physician product usage.
- HCP estimated product usage data may only be used in a professional and responsible manner and must never be used to badger, embarrass, harass, intimidate, pressure, coerce or punish HCPs in any way.
- HCP estimated product usage data is treated as Company confidential information. Field Sales must not disclose this information to any person outside the Company or to any person within the Company who does not have a need to know this information. Field Sales must take appropriate precautions to ensure the privacy of such information. Failing to do so or misusing the data may result in disciplinary action.



CHAPTER 3

# Gifts, Entertainment, Promotional Aids and Educational Items

Aclaris is committed to ensuring that interactions with persons or organizations able to purchase, prescribe, or recommend Aclaris products are both lawful and consistent with the highest standards of ethics and good business practices. This commitment guides the Company's policy on the provision of gifts, meals, and entertainment, which incorporates, among other guidance, the PhRMA Code, Guidance by the Department of Health and Human Services Office of the Inspector General, and the California Comprehensive Compliance Program Law. Additionally, several states have enacted laws that limit or prohibit gifts, meals, or entertainment to HCPs, certain entities, and/or state employees.

Employees must not offer or provide anything of value with the intent of directly or indirectly influencing or encouraging the recipient to purchase, prescribe, or recommend a product, or as a reward for previously doing so. Where permissible under this policy, things of value must be modest and provided only on an occasional basis.

- Payments in cash or cash equivalents (such as gift cards) must never be provided or offered to HCPs. Gifts for the personal benefit of an HCP (such as flowers, sporting or entertainment tickets, electronics items, etc.) are never to be provided or offered.
- **No entertainment or other leisure or social activities should be provided by any employee (either directly or indirectly) to HCPs.**

Many countries as well as various states in the U.S. restrict the types of items that can be provided to HCPs. It is important that any item intended to be provided to HCPs be first approved by PRC. Following are examples of some items that are permitted and examples of items that are not permitted.

| | Examples | Permitted or Not Permitted |
|---|---|---|
| **Promotional Material** | *Examples include:* Leave Behinds, Patient Education Materials, etc. | Permitted: Must first be approved by PRC. |
| **Promotional Aids** | *Examples include:* Inexpensive pens or notepads | Not Permitted in the U.S.: Promotional Aids must not be provided to U.S. HCPs because such items are prohibited by the PhRMA Code. |
| **Educational Items and Items of Medical Utility** | *Examples include:* Anatomical models, textbooks, reprints, journal subscriptions, etc. | May be permitted if, after approval by PRC: - It is provided in accordance with local laws and regulations, of modest value, designed primarily for the education of patients or HCPs, and beneficial to enhancing the provision of medical services and patient care. |

CHAPTER 4

# Meals Policy

## Guidance for Field Sales

Field Sales may offer a meal in connection with a sales presentation only if:

- **the sales presentation provides scientific or educational value**
- the meal provided complies with state law requirements/restrictions
- meals may only be provided on an occasional basis (no more than 2 per month) and must be:
  - **limited to in-office or in-hospital/clinic settings unless relating to an approved Speaker Program**
  - modest and reasonable according to local standards, and in no event should exceed $25 per person inclusive of tax and tip for in-office meals; the limit for NJ-licensed prescribers is $15 per person
  - devoid of any entertainment or recreational activity
  - provided in a manner conducive for informational communication
  - limited to HCPs and appropriate staff; no spouses or other non-staff guests are permitted
  - provided in the presence of the Field Sales colleague (i.e., take-out meals are prohibited)
- the disclosable value of a meal is calculated by taking the total cost of the meal and dividing it by the number of actual participants partaking in the meal. Each participant in a meal must be appropriately documented in the expense reporting system. Prescribers, nurses (e.g., RNs, NPs, APRNs), physician assistants, pharmacists and medical students must be listed by name in the expense reporting system.

**Q&A**

**Who are considered Field Sales colleagues?**

*Aclaris considers all sales representatives and their immediate managers (RMs) to be Field Sales.*

CHAPTER 5

# Exhibits and Medical Conferences

Exhibits and displays can take the form of promotional exhibits or scientific exhibits. An exhibit booth or display table at an organization's conference or event may be permitted if:

1. Aclaris does not pay more than fair market value (FMV) for the display opportunity and
2. the location of the display must be separate and apart from any independent educational activity.

| Commercial and Promotional Exhibits | Scientific and Disease Awareness Exhibits |
|---|---|
| • Let your Regional Manager (RM) know if there is a potential local exhibit/display opportunity for Aclaris.<br>• The exhibit/display request must be approved beforehand (at least one month in advance)<br>▸ by the VP of Professional Relations where the exhibit cost is $5,000 or less;<br>or<br>▸ by the Legal Department where the exhibit cost is more than $5,000 | • The exhibit/display request is approved beforehand (at least one month in advance)<br>▸ by the VP of Medical Affairs and by PRC |
| • For exhibits where the cost is more than $5,000, the Legal Department reviews the Exhibitor Agreement (if any) – agenda, brochure and forms must be provided for review | • Medical Affairs will be particularly interested in the location and proximity of the scientific/ disease awareness booth to the commercial booth |
| • Only Product Promotional material and signage approved by PRC for the event may be used at the exhibit/display | • Only scientific materials approved by Medical Affairs and the Legal Department may be used at the exhibit |
| • Only Field Sales and Commercial Colleagues may staff a promotional booth | • Only Medical Affairs, including MSLs may staff a scientific/disease awareness booth |

## Q&A

**Can we include a coffee station, provide pastries or have a bowl of chocolates (of nominal value) at the Aclaris exhibit booth at an organization's non-accredited portion of their event?**

*Yes, however, a placard stating that Minnesota-licensed HCPs may not take any of the candy/beverage must be displayed. In addition, the candy bowl/snack/beverage must be of nominal value and must not exceed $25 in total value.*

**Suppose several Aclaris employees including Field Sales and MSLs are attending a conference. We all arrange to meet for lunch (or dinner) to get to know one another better. Can the most senior person attending also invite an HCP to join us?**

*No, Field Sales colleagues and MSLs may not meet jointly with HCPs. Field Sales and MSL colleagues must keep their roles and responsibilities separate. Avoiding these kinds of joint meetings reduces the risk of participating in discussions or presentations which may be inappropriate for the Field Sales or MSL colleague.*

CHAPTER 6

# Sales and Commercial Are Not Involved with Grants

The Company may consider grant requests from a broad range of health-related organizations. Grant applications must be directed to the Medical Affairs Department. If an employee is approached regarding a grant question and/or request, the requestor should be informed that grant requests or inquiries must be sent directly to **Grants@aclaristx.com.**

The Medical Affairs Department manages the grant application process, with oversight from the Grants Committee. The Company provides grants to support healthcare education, charitable, and general philanthropic initiatives, including independent medical education programs, Investigator Initiated Studies (IIS), scientific conferences, development of health education materials, patient education programs, and healthcare-related and disease-awareness community activities. Grants may be awarded to hospitals, universities, charitable or social welfare organizations, health-related organizations, and other institutions.

The Grants Committee shall deny any grant requests that it receives from Commercial Colleagues, which are forwarded to it by Commercial Colleagues, or which have been first reviewed by Commercial Colleagues. Requesting organizations are required to submit their grant requests or inquiries directly to **Grants@aclaristx.com.** No grant may be provided, directly or indirectly, as an inducement or reward for purchasing, prescribing, recommending, or providing other support for Aclaris products.

After the Grants Committee has decided whether to approve or deny a request, a Medical Affairs colleague (or designated member of the Grants Committee) shall provide written notice of such determination to the requestor. **Only Medical Affairs or designated members of the Grants Committee may communicate funding determinations or authorize delivery of grant proceeds to recipients.**

## Q&A

**One of my target aesthetic dermatologists has expressed an interest in conducting her own research using Aclaris product or perhaps would like to be an investigator for an Aclaris trial already underway. Who should she contact for more information?**

*Any HCP can contact Medical Information* ***(MedInfo@aclaristx.com)*** *to inquire about support for clinical trials. Proposals for Investigator Initiated Studies should be sent directly to* ***IIS@aclaristx.com.*** *Medical Affairs will follow-up regarding their interest in investigator initiated research. In addition, information relating to Aclaris clinical programs is publicly available on the Company website –* ***www.aclaristx.com.***

CHAPTER 7

# Advisors and Consultants

Aclaris enters into consulting arrangements with HCPs for a range of services including business-related counseling relevant to current and/or future products, Scientific Advisory Boards, Expert Input Forums, and clinical program design and implementation, among others.

An HCP consulting arrangement is permissible as long as:

- There is a legitimate business need for the services;
- The consultant is selected based on his or her expertise and knowledge and not to gain access or to influence prescribing habits;
- The number of consultants selected is supported objectively and is appropriate to the business need;
- A written contract is executed prior to the provision of services that specifies the nature of the services and the basis of payment for those services;
- The term of the agreement is for at least one year;
- The services are provided as outlined in the written contract; and
- Any compensation does not exceed the approved internal fair market value rate.

HCP consultants who are members of a formulary or clinical practice guidelines committee must disclose to that committee the existence and nature of their relationships with Aclaris. This disclosure requirement extends for at least two years beyond the end of the consulting arrangement.

Consultants must provide an actual service. For example, passive activities such as time spent merely receiving a marketing presentation are not considered bona fide services and are not compensable.

**The objective in entering into a consulting arrangement with an HCP must never be to:**

- Establish or improve Aclaris' relationship with the HCP;
- Gain or improve access to the HCP; or
- Reward past prescribing or induce future prescribing.

CHAPTER 8

# Speaker Programs

A Speaker Program is a promotional activity provided by the Company during which an approved speaker, generally an external HCP under contract with the Company (Speaker), presents information on products, disease states or other healthcare topics to a group of HCPs and/or other appropriate attendees. Promotional Speaker Programs allow Aclaris to present experts to educate HCPs about our products and other relevant topics.

The FDA considers HCP speakers to be representatives of the pharmaceutical company for whom they are speaking on behalf. Thus, Aclaris is responsible for the content and conduct of its Speaker Programs. This includes all information presented by the Speaker, any payments related to the program, as well as the venue and other details of the event.

**All Speaker Program materials (including presentation, agenda and slide deck materials) must be approved in advance by PRC.** PDF copies of program invitations that mention a Company product which are distributed to HCPs must be accompanied by the product full prescribing information (PI).

## Speaker Selection and Training

Through its Speaker Programs, the Company retains qualified HCPs to speak on the Company's behalf concerning its products and the diseases that they treat, consistent with the products' on-label uses and disease awareness guidelines.

- Commercial Operations is responsible for the selection and retention of Speakers. All HCPs engaged as Speakers must at a minimum meet the following criteria:
  - The Speaker must be a licensed Physician, Nurse Practitioner (NP), or Physician Assistant (PA) who has clinical expertise, excellent public speaking skills, and prior public speaking experience in the pharmaceutical or dermatology medical arena.
  - Prospective Speakers must not be debarred or excluded by the FDA or Office of Inspector General (OIG), and must meet all the other screening requirements that pertain to consultants.
  - Speakers must not be selected based on an explicit or implicit understanding, intent, or desire that they will prescribe, purchase, or recommend Company products because of their participation in the Speaker Program.
- To remain active in the Speaker Program, each Speaker must attend Company training at least once per year and each Speaker must conduct at least two speaker programs per calendar year.
- The total annual compensation for speaking fees must not exceed the per HCP maximum established by the Company.

## Scheduling and Conducting a Speaker Program

Requesting and managing Speaker Programs should be done online via the Speaker Bureau portal. There are 3 types of Speaker Programs: 1) live dinner programs; 2) peer-to-peer in- office programs; and 3) web-conferencing programs.

| Live Dinner Program | Peer-to-Peer In-Office Program | Web-Conference Program |
|---|---|---|
| Speaker is physically present and conducts presentation from an approved venue location. | Speaker is physically present and conducts presentation at the HCP's office location | Speaker is remote and conducts the presentation in real-time over the internet. |

Each live dinner, peer-to-peer in-office, and web-conferencing Speaker Program should have a minimum of 3 HCPs registered 5 days before the scheduled program. Programs with less than the minimum number of registrants shall be cancelled. The Speaker Bureau portal is designed to notify relevant Field Sales colleagues of programs with low numbers that are in jeopardy of being cancelled.

At least one Field Sales colleague must attend the entirety of each Speaker Program. The Field Sales colleague has three major responsibilities in relation to Speaker Programs:

### #1 Prepare for the Program

- The Field Sales colleague must bring the most current copy of the approved slide deck (or otherwise ensure that the Speaker has the most current copy) and be prepared to project the slides using his/her laptop. The Speaker cannot skip required safety slides or conduct a program without presenting any slides at all.

### #2 Monitor Attendance

- Ensure that everyone signs-in.
- Ensure that there are only appropriate attendees in the audience: (i) appropriate HCPs and appropriate non-prescribing medical staff may attend; (ii) HCPs licensed in MN or VT must not partake in any food/beverage; (iii) no spouses or other guests may attend; and (iv) HCPs with Excluded Specialties must be politely asked to leave the program. **Pediatricians may not attend Aclaris Speaker Programs.**
- Programs with only 1 attendee must be cancelled. The Field Sales colleague must let the Speaker and the attendee know that this is Company policy and no meal or beverages may be provided. Also, it is not permissible to have only attendees from a Speaker's practice attend a Speaker Program.
- Within 48 hours of completion of the Speaker Program, be sure to close out the program using the Speaker Bureau portal.

## Q&A

**Who's appropriate as a Speaker?**

*Only an HCP who is a licensed Physician, Nurse Practitioner (NP), or Physician Assistant (PA) with dermatology or medical aesthetic practice expertise may be a Speaker for Aclaris.*

**Who may attend a Speaker Program?**

*Appropriate prescribers, licensed healthcare professionals, non-prescribing medical staff, or other healthcare professionals connected with the provision of healthcare may attend Company Speaker Programs. Spouses, guests or persons who are not medical staff may not attend Company Speaker Programs. In addition, pediatricians and pediatric dermatologists are prohibited from attending.*

| Appropriate Attendees | Inappropriate Attendees |
|---|---|
| *Examples of Appropriate Prescribers:* Dermatologist, Nurse Practitioner, Physician Assistant | *Examples of Inappropriate Prescribers:* Pediatrician, Pediatric Dermatologist |
| *Examples of Appropriate Licensed HCPs:* Licensed Practical Nurse (LPN), Registered Nurse (RN) | *Examples of Inappropriate HCPs:* Licensed massage therapist, laser technician, facial technician |
| *Examples of Appropriate Medical Staff:* Medical Assistant, Medical Student, Aesthetician | *Examples of Inappropriate Staff:* Billing clerk, receptionist, office manager, non-medical family members of the HCP's clinic |

### #3 Monitor Content

- The Field Sales colleague must introduce the Speaker and ensure that it is clearly stated that Aclaris is sponsoring the presentation.
- The Speaker may not provide any off-label information in response to any questions raised by audience members. Have them contact Medical Information, instead.

## Q&A

**What should I do if a Speaker presents off-label information during his or her presentation or provides off-label information in response to a question?**

*You should:*

- *Promptly and courteously clarify to the audience that the off-label information provided is not within product labeling and state the labeled indication(s). This should be done as soon as possible after the Speaker has made the statement.*
- *Remind the Speaker after the presentation that Company policy prohibits providing any off-label information or information on extraneous topics.*
- *When you close out the program in the Speaker Program system, indicate, as prompted in the system, that a violation was committed by the Speaker.*

CHAPTER 9

# Privacy

Personal Information (PI) includes any information that alone or in combination with other data can be used to identify a person. Sensitive Personal Information (SPI) is a subset of Personal Information which includes personal information about a person's physical or mental health (e.g., a person's medical history, physical or mental condition, diagnosis or treatment or the identity of the person's health care provider or health insurer) that, in combination with certain identifiers, such as name, birth date, or social security number, can be used to identify a specific individual.

There are many federal and state laws applicable to the use of Personal Information and Sensitive Personal Information. Regardless of the circumstances under which PI is disclosed, when an individual chooses to share such information with a person they trust, they generally expect the person to hold that information in confidence and to keep it secure. Aclaris respects this expectation and is committed to appropriately protecting Personal Information.

It is important that you do not request or collect SPI for any reason unless you have express prior approval to do so. For example, you may not review charts or documents containing SPI. Avoid situations likely to lead to the inadvertent disclosure of SPI, such as private conversations between HCPs and patients. In the event an HCP or other person exposes you to SPI, you should not document or reproduce the information in any media or form. You must strictly maintain the confidentiality of such information.

Any suspected breach of security of PI or SPI should be immediately reported. Lost or stolen computers or other devices should be reported to your manager and the Helpdesk. Any incidents of potential unauthorized access to Company data should be reported to the Helpdesk as well as the Legal Department.

## Business Associate Agreements

One of the most important federal healthcare laws in privacy is called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA was significantly expanded by the Health Information Technology for Economic and Clinical Health Act (HITECH). HIPAA and HITECH impose strict limitations on the use and disclosure of SPI by "covered entities" and their "business associates."

Some HCPs will request a Business Associates Agreement (BAA) when what they really are seeking is a confidentiality agreement to protect their patients' SPI in the event it is inadvertently disclosed in your presence. To address such requests, you are permitted to offer the HCP the Aclaris-created Privacy Agreement. No changes can be made to the Privacy Agreement and do not sign any other type of agreement.

### Q&A

**May I sign a BAA if a physician insists and to avoid being shut out of the practice?**

*No. You must not sign a Business Associate Agreement, even if required by an HCP to be allowed access to a facility. You may, however, sign and provide an Aclaris-created Privacy Agreement, which should be sufficient to satisfy the HCP's concerns about patient privacy. If the HCP continues to insist on a BAA, please promptly contact the Legal Department.*

CHAPTER 10

# Interactions with Patients and Patient Advocacy Groups

The Pharmaceutical Research and Manufacturers of America (PhRMA) has issued guidance entitled *Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines,* which provides guidance on ways to ensure that patient and consumer communications provide accurate, accessible, and useful information.

When communicating with patients and patient advocacy groups it is important to provide useful and understandable information about conditions and treatment options that will help patients partner with their healthcare providers to make more informed decisions about their treatment. The goal of attending patient/community events or patient advocacy group events should be to foster more informed conversations between patients and their HCPs about patients' health and treatment options.

PRC-approved patient education materials can be provided to patients and patient advocacy groups through HCPs' offices or at patient-focused events such as health screenings, state fairs, or patient advocacy events where the Company has an approved display or exhibit. In cases where the Company has a display or exhibit, a very modest snack (e.g., fruit, granola bars, pastries or non-alcoholic beverages) may be available for patients who visit the booth and the snack should be consistent with the level of interaction you are having with them. People who are not Aclaris employees, including HCPs, should not work or host the Aclaris booth.

**When interacting with patients or patient advocacy groups:**

- Always disclose that you are an Aclaris employee.
- Use only PRC-approved materials intended for patient education and limit the discussion to information contained in these materials.
- Provide fair and balanced information.
- Do not provide off-label information.
- Do not provide advice to patients about their condition or treatment, regardless of your professional training or position at Aclaris. Refer them to their HCP to discuss treatment options.
- Do not discuss competitor products, except to the extent that they have been included in PRC-approved patient materials. Along these lines, do not encourage patients to switch their medication to an Aclaris product.
- If you receive a report of an adverse event or product quality complaint, report the information to **safety@aclaristx.com** within 24 hours.
- Safeguard the confidentiality of Personal Information (PI), including Sensitive Personal Information (SPI).

# CHAPTER 11 Prescription Drug Samples

HCPs may receive free pharmaceutical drug product samples to give to patients so that they can evaluate the efficacy and tolerability of our products for the patient before filling a prescription. Samples also provide HCPs an opportunity to become familiar with a drug and its properties, thereby enhancing their ability to make appropriate prescribing decisions. The distribution of samples is highly regulated under federal and state law, and the misuse of drug samples can have severe implications.

The Prescription Drug Marketing Act of 1987 (PDMA) is the key federal law governing the distribution of drug samples.

The following are key points to ensure compliance:

- It is illegal to sell, purchase, or trade, or offer to sell, purchase or trade, prescription drug samples. Samples may be provided only to licensed HCPs eligible to receive samples and only if they are expected to distribute them for free for on-label use by their patients. Aclaris is required to independently verify HCP licenses before they may provide samples to such HCPs.
- The number of samples allocated must be based on the expected on-label use of the product. Samples must not be provided to HCPs in quantities that may appear to be intended as an inducement to use Company products (i.e., a kickback). Providing samples in quantities or dosages based on off-label use is not permitted.
- Individual sample units cannot be altered in any way either before or after they are delivered to an HCP.
- Only licensed HCPs authorized by their states' laws to receive and prescribe medications may sign a request for samples. Some states permit mid-level practitioners (e.g., physician assistants, nurse practitioners) to prescribe drugs but either (1) do not allow them to receive samples; or (2) only allow them to receive samples under certain restrictions (e.g., supervising physician must sign agreement to permit mid-level practitioner to receive samples). Aclaris must comply with such state requirements.

## Field Sales employees are required to personally witness the signature on every sample request.

- Samples may not be provided to HCPs for their personal use or taken by employees for their personal use. "Personal use" includes use by family or friends.
- Any loss or theft of samples must be reported immediately to Sales Operations and the Compliance Office. Significant losses and thefts must be reported by the Company to the FDA within five days of becoming aware of the loss or theft.
- "Sample – Not for Sale" language is required by the FDA.
- At least one package insert must be left with each type of sample provided to the HCP.
- PDMA requires at least 1 physical inventory count and full reconciliation in a 12-month period.
- Expired samples may not be given to HCPs under any circumstances and must be returned for destruction in accordance with the process in your *Sample Handbook.*

CHAPTER 12

# Medical Science Liaisons

Medical Science Liaisons (MSLs) are credentialed (i.e., MD, PhD, or PharmD) field-based Medical colleagues with expertise in the therapeutic and disease areas of interest to the Company. MSL responsibilities are focused on medicine development and include communicating scientific and medical information through scientific exchange, including responding to HCPs' unsolicited medical requests.

MSLs are precluded from participating in any activities that are governed by promotional standards, except upon the express prior approval of the VP, Medical Affairs.

## Relationships/Interactions with other Departments

The decision to involve a MSL in activities governed by promotional standards can be made only by the VP, Medical Affairs. MSLs have no sales objectives or accountability for prescribing or sales of any Company product and are required even to avoid any situations which could create the appearance that they have such responsibilities. An MSL may not comment on or make suggestions with respect to the diagnosis, treatment, or circumstances of a specific patient. Field Sales are permitted to have regular, scheduled internal interactions or meetings with MSLs for business planning or sharing appropriate information.

**MSLs must not:**

- Conduct sales calls with Field Sales
- Use their relationship with HCPs to provide access to those HCPs for Field Sales
- Provide billing/coding services to HCPs
- Provide guidance on practice management or guidance on building a practice to HCPs
- Make patient-specific treatment recommendations or otherwise provide patient-specific medical advice

**All unsolicited requests for off-label information must be sent to Medical Information and may not be forwarded directly to or discussed with MSL colleagues.**

CHAPTER 13

# Publications

As part of our commitment to publishing the results of Company-sponsored patient research studies, Aclaris supports the publication of manuscripts associated with these studies. The Company also supports other types of publications, such as abstracts, congress presentations and review articles.

First and foremost, publications are not marketing tools. While a publication may eventually be used in a promotional context, the planning and development of a publication must be true to the data and independent of commercial strategy or messaging. Second, employees must ensure that any engagement of HCPs to author or produce publications does not give rise to inappropriate financial relationships or influence.

Importantly, the process by which authors are selected and compensated, if not structured appropriately, may violate federal or various states' anti-kickback statutes. For example, if an HCP is being paid to author publications but in reality, is just "rubber-stamping" an article written by a third party, the government may look to whether that HCP has been chosen and/or paid as an inducement for his or her continued or increased prescribing of a product.

Publications are managed by Medical, Clinical and Regulatory colleagues to ensure that patient study results are published.

Aclaris has adopted the authorship criteria established by the International Committee of Medical Journal Editors (ICMJE) and PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results.

Only individuals who meet all the ICMJE criteria should be named as authors on medical/scientific publications. In addition to the ICMJE criteria, authors of a Company-supported publication must fully comply with all applicable disclosure obligations. Authors must acknowledge in the publication the individuals who provided editorial support, the funding source, and the author's relationship with Aclaris. All external authors must enter into written agreements describing the scope of work to be performed and the agreement must include representations that they will adhere to authorship criteria and disclosure obligations.

CHAPTER 14

# Federal, State and International Transparency Reporting and Restrictions

There are several jurisdictions where Aclaris may be required to make disclosure reports or required to place caps on the amount it spends with healthcare professionals.

| Jurisdiction | Disclosure Obligation |
|---|---|
| **Federal** | The Open Payments provisions of the Affordable Care Act (also referred to as the "Sunshine Act") requires the Company to report payments and transfers of value from Field Sales colleagues, as well as those made by headquarter personnel, including Medical Affairs and Research and Development in relation to "covered drugs" (i.e., those that are available for reimbursement). The law extends to any payment or transfer of value provided to another party at the direction of or on behalf of a physician or teaching hospital, and any payment or transfer of value provided to a third party that is then passed through to a physician or teaching hospital when the Company knows the identity of the physician or teaching hospital.<br><br>In addition, data relating to samples distributed to HCPs must be submitted on an annual basis through the FDA submission gateway. |
| **California** | Companies shall adopt a comprehensive compliance program which sets specific dollar limits on gifts, promotional materials and activities. |
| **Chicago** | Beginning July 1, 2017, Field Sales who market or promote pharmaceuticals within the City of Chicago for 15 calendar days or more per year are required to obtain a license. The license application fee is $750 per individual for a one-year licensing term and may be renewed annually. Fingerprinting, online education and continuing education are required. Information relating to the marketing/promotion and items of value provided to HCPs, including specifics relating to interactions with HCPs must also be disclosed. |
| **Connecticut** | Beginning July 1, 2017, Companies must provide annual reports on any fees or transfers of value provided to Advance Practice Registered Nurses engaged in independent practice in the state. |
| **District of Columbia** | All representatives must secure a license to legally detail in person in D.C. and the Company must report certain product advertising/marketing expenditures (certain employee total compensation figures are counted in the costs). The Company must also report items of value over $25 provided to HCPs who provide healthcare in the District.<br><br>Members of the D.C. Medication Advisory Committee must not receive gifts, including meals or remuneration, for speaking or consulting, no matter how nominal the value. |

| Jurisdiction | Disclosure Obligation |
|---|---|
| **Louisiana** | Effective August 1, 2017, manufacturers engaging in marketing of prescription drugs in Louisiana must report quarterly to the Louisiana Board of Pharmacy the WAC prices for those drugs. |
| **Maine** | Pursuant to Maine state statute 22 M.R.S.A. §2685, the Company must pay an annual fee to the Maine Department of Health and Human Services if its products are provided to Maine residents through MaineCare (Medicaid) or Maine's Elderly Low-cost Drug Program. |
| **Massachusetts** | The Company must track and annually report expenditures of $50 or more to Massachusetts "covered recipients", regardless of where the event takes place, to the extent such expenditures are not reported under the Federal Sunshine Act for the applicable "covered recipient". |
| **Minnesota** | The Company must report certain payments if they total $100 or more per year and are made to APRNs, NPs, PAs and dental therapists.<br>The Minnesota Gift Ban Law prohibits gifts more than $50/year/HCP in the aggregate among all employees. Therefore, Company policy prohibits gifts to MN-licensed practitioners.<br>In addition, meals to MN practitioners are prohibited, including in-office meals and nominal food and beverage except in connection with only limited types of engagements. |
| **Nevada** | Nevada Marketing Code of Conduct requires companies to adopt a marketing code of conduct and make a declaration of compliance.<br>Manufacturers are required to submit a list of sales representatives marketing prescription drugs in the state by October 1st, annually, to update the list within 30 days of any new hire, and to make certain annual disclosures on or before March 1st. |
| **New Jersey** | Prescribers licensed in New Jersey are prohibited from partaking in meals that are not modest (defined as exceeding $15/person) at company-sponsored events or from receiving compensation exceeding $10,000 annually in the aggregate from pharmaceutical manufacturers. |
| **Ohio** | In July 2017, the Ohio Board of Pharmacy clarified that Ohio-licensed prescribers must possess a Terminal Distributor of Dangerous Drugs (TDDD) license in order to receive samples and free units of controlled substances and certain non-controlled prescription drugs. Therefore, samples of Aclaris product may only be provided to Ohio-licensed HCPs after verification that he/she has a TDDD license. |

| Jurisdiction | Disclosure Obligation |
|---|---|
| **Vermont** | Vermont prohibits all gifts to HCPs, which includes all HCP meals, including in-office meals and meals of nominal value (there is a limited exception for: (i) bona fide service contracts and (ii) refreshments or other snacks at a booth at a convention/congress).<br><br>Vermont also prohibits paid market research surveys involving VT licensed HCPs. The restriction applies whether the survey is conducted directly by Aclaris or through an independent third-party survey research organization. Distribution of samples, coupons and vouchers must be reported. The Company must also self-report any violations of the Vermont Code. |

## Restrictions on Interacting with Federal and State Employees

Almost all states have restrictions on interactions with state employees (including HCPs employed by state institutions). Consult with the Legal or Compliance Department if you have any questions concerning restrictions for a particular state employee. A summary of the most significant restrictions for state employees is provided below.

| Jurisdiction | State Law Restriction |
|---|---|
| **Colorado** | State employees may not receive anything of value worth more than $50 from a company (as a whole, not by employee). |
| **Connecticut** | Public officials and state employees may not accept anything of value, including but not limited to gifts and loans from a lobbyist. |
| **Kentucky** | Public servants (and their spouses or dependent children) may not receive anything of value worth more than $25 per calendar year. |
| **Louisiana** | State employees are prohibited from performing certain compensated services for pharmaceutical companies.<br><br>State employees have a $60 cap on food, drinks, and refreshments provided during a single event. |
| **New York** | State and local employees are prohibited from receiving gifts. |

Government employees are subject to strict and complex conflict of interest rules. Because of this, all sales, marketing and promotional interactions with federal government employees require advance approval by the Compliance Department. “Federal government employees” include physicians, dermatologists, pharmacists, other healthcare practitioners as well as purchasing personnel employed by the Department of Veterans Affairs (VA), Department of Defense (including uniformed military personnel), Indian Health Service, National Institutes of Health (NIH), and the Public Health Service (PHS).

CHAPTER 15

# Raising Compliance Concerns

Aclaris will not tolerate retaliation against any employee who raises a business practices or compliance issue. Any employee who raises such an issue will be protected from retaliation. This protection extends to anyone giving information in relation to an investigation. However, Aclaris reserves the right to discipline anyone who knowingly makes a false accusation, provides false information to Aclaris or has acted improperly.

| | **Hotline for Reporting: (844) 735-7386** |
|---|---|
| **Open Door Policy:** | Aclaris has an "Open Door Policy" and encourages colleagues to discuss all issues, concerns, problems and suggestions with their immediate supervisors or other managers without fear of retaliation. |
| **Hotline:** | The Aclaris whistleblower hotline allows employees to report a concern or to get information or advice anonymously. |
| **Web-Reporting Tool:** | Visit **www.AclarisComplianceHotline.com** to make an online report. Your confidential and anonymous report will instantly and discreetly be forwarded to appropriate Company personnel. |
| **Email:** | You may also email **ComplianceOfficer@Aclaristx.com** |

Aclaris has a Chief Compliance Officer and an Executive Compliance Committee to help implement and monitor its compliance program. Every employee plays a role in compliance, however. You are responsible to become familiar with and abide by Company policies and procedures, and requirements communicated to you through departmental SOPs and training programs. All employees who may, as a part of their role, interact with HCPs will receive compliance training, which addresses Company policies and procedures.

Our compliance program supports prompt response and corrective action as appropriate under the circumstances. All employees are critical to maintaining an effective compliance system. You are responsible for raising concerns about risks to the Company — ideally, before these risks become actual problems. If you believe that there has been a violation of local, state or federal law, law of a foreign country, or specific policy or procedure, you must report that information immediately to your supervisor or to the Chief Compliance Officer. Whenever you are in doubt, it is best to raise your concern. By raising concerns, you allow management the opportunity to address potential problems.

It is expected that all referred compliance concerns will be carefully reviewed, thoroughly and thoughtfully investigated in a timely manner, and appropriately resolved. Upon conclusion of an internal investigation, corrective action and preventative measures will be determined and implemented as appropriate. In addition, Aclaris monitors and periodically audits applicable processes and personnel for compliance with policies and procedures, as well as relevant laws, regulations, and industry guidelines. The Company may also conduct "for cause" audits and reviews, as needed, as part of its investigation procedures. All employees must cooperate with any investigation of a known or suspected violation and answer all inquiries truthfully. Any employee who withholds information or attempts to mislead or misdirect an investigation is subject to disciplinary action, up to and including termination.

# Notes

# Notes

Responsibility & Integrity.
**It begins here.**


**Illuminating Science. Empowering Patients.**

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