SK life science
a subsidiary of SK biopharmaceuticals

Partner with Compliance

US Commercial Field Compliance Manual

Compliance Guidelines for Field Sales Interactions

Version 4.0
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Our Compliance Program

- At SKLSI, we are committed to supporting an effective healthcare compliance program
- All SKLSI employees must act with honesty and integrity
- SKLSI Field Associates are responsible for speaking up about potential unlawful or unethical conduct

At SK Life Science, Inc. ("SKLSI"), we are all responsible for understanding the framework in which we operate, the issues that impact our business, and for acting with integrity, always. While we strive to do the right thing every day, identifying the right thing is not always clear.

While we hope this Compliance Manual will serve as a comprehensive source of guidance, it cannot address every situation you could potentially encounter. If you have any questions about the Compliance Manual, or if you need additional guidance, please reach out to your manager, Compliance, or Legal. The members of the SKLSI leadership team are also available to answer any questions or concerns you may have related to company practices.

The Compliance Manual

The US Commercial Field Compliance Manual ("Compliance Manual") applies to all field-based Commercial employees of SKLSI including but not limited to:

- Area Executive Directors (AEDs)
- Regional Sales Directors (RSDs)
- Market Development Managers (MDMs)
- Key Account Managers (KAMs)
- Field Sales Professionals

Hereinafter referred to as "Field Associates."

Note: *Medical Science Liaisons (MSLs) are not fully covered within this Compliance Manual and should refer to the US Field Medical Compliance Manual.*

Q: What constitutes a violation?

A: Any activity that does not comply with the Compliance Manual, SKLSI Code of Conduct, internal policies or procedures, or applicable laws, regulations, and industry guidelines.

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Our Compliance Program *(continued)*

The Compliance Manual provides guidance for your activities and behavior while representing SKLSI. It includes an overview of relevant policies and procedures implemented to maintain compliance with applicable laws, regulations, and industry guidelines in a manner consistent with SKLSI values. By acting in accordance with this Compliance Manual as well as applicable laws, policies, and guidelines, we fulfill our mission of helping to improve Patients' lives.

Red, underlined terms are included in the Compliance Manual **Glossary** for easy reference.

Speak Up!

We don't expect you to know the answer to every situation, but we do expect you to speak up and ask when you don't know the appropriate action to take or have concerns about potential compliance violations. When a complex issue arises, we expect you to exercise good judgment and seek advice.

Reporting Concerns

Any employee or individual acting on behalf of SKLSI must report any suspected violations of company policy or law.

You can reach the SKLSI Compliance team by contacting:

Email ..... compliance@sklsi.com

Anonymous reports can also be made by contacting the hotline by one of the following means:

Phone ..... (833) 490-0007
Web ..... www.lighthouse-services.com/sklsi
Email ..... reports@lighthouse-services.com *(include "SKLSI" in the subject line)*
SK Group Whistleblower Hotline ..... https://ethics.sk.co.kr/

Q: What should I do if I'm unsure if something I observed is considered a violation?

A: Speak up and ask questions! Contact your manager or SKLSI Compliance using the contact information listed in the Compliance Manual.

Q: What do I do if SKLSI policy does not appear to align with a federal or state law?

A: The state or federal requirement will govern your interactions with Healthcare Professionals (HCPs) licensed or located in that state or country. When in doubt, contact your manager or SKLSI Compliance for guidance.

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Non-Retaliation & Confidentiality

SKLSI has established a non-retaliation policy and will not retaliate against anyone who seeks advice or reports potential compliance or ethics concerns in good faith.

SKLSI handles all reports of potential compliance concerns with sensitivity and discretion. To the extent possible, SKLSI will maintain the confidentiality of those reporting potential compliance concerns as well as individuals involved in the report.

Investigation & Discipline

Compliance investigates all reports of potential compliance violations and determines an appropriate response, which may include disciplinary action up to and including termination of employment, if an alleged violation of a law, code, policy, or guideline is substantiated.

At SKLSI, we expect you to:

- Know the rules
- Avoid assumptions and ask questions when you are unsure
- Seek clarification
- Speak up
- Stay aware

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SKLSI Policies

- SKLSI is committed to conducting business in a transparent and ethical manner and in accordance with all federal and state laws, regulations, and industry codes and practices
- SKLSI Commercial Associates are expected to comply with applicable laws, regulations, and guidelines regarding ethical professional behavior

SKLSI POLICIES

SKLSI policies and procedures have been developed to ensure our activities are consistent with industry laws, regulations, and guidelines (including, but not limited to, federal and state Anti-Kickback and Bribery laws, the Food Drug & Cosmetics Act, federal and state False Claims Acts, and the PhRMA Code). The requirements established by these principles and standards provide a foundation for SKLSI Associates to operate with integrity and honesty. Every employee must abide by current best practices and maintain compliance with all applicable policies and procedures.

Relevant SKLSI policies for SKLSI Commercial Associates include, but are not limited to:

- **Code of Conduct** — Establishes the framework of principles and standards by which SKLSI and its employees conduct business in a lawful, ethical, and honest manner.
- **Healthcare Professional Interactions Policy** — Governs all interactions conducted between SKLSI Associates and any US-licensed HCP on behalf of the Company.
- **Patient & Patient Organization Interactions Policy** — Governs all interactions conducted between SKLSI Associates and any patient, caregiver, or patient organization on behalf of the Company.
- **Anti-Bribery & Anti-Corruption (ABAC) Policy** — Governs all business activities performed by SKLSI Associates for which ABAC laws and regulations may apply in those jurisdictions where the Company does business.
- **Government Officials Interactions Policy** — Governs all interactions conducted between SKLSI Associates and any international, federal, state, or local government official on behalf of the Company.
- **Fee-for-Service Arrangements Policy** — Governs the contracting of consultants (e.g., HCPs, Non-HCP KOLs, Patients, etc.) at SKLSI, including their selection, compensation, and engagement.

Q: I think an HCP would be a great advocate for XCOPRI at speaker programs because they prescribe so much of it for their patients. Can I nominate them for the speaker bureau?

A: No. The *Healthcare Professional Interactions Policy* prohibits providing anything of value in exchange for purchases of our products. If even one purpose of the payment (in this case, the speaker honoraria) is to reward for prior purchases (in this case, the prior prescriptions), the entire arrangement may be in violation of the *Healthcare Professional Interactions Policy*.

Q: Why can't I proactively discuss Off-Label uses of SKLSI products with HCPs if HCPs can prescribe for off-label uses?

A: To ensure the safety, efficacy, and security of SKLSI products, SKLSI Associates must not promote the sale of products that are misbranded or adulterated. This includes promoting products for unapproved, off-label uses. The ability of physicians to prescribe off-label is distinct from the legal requirements regarding the promotion of SKLSI products.

If an HCP asks an unsolicited question about an off-label use of an SKLSI product, SKLSI Commercial Associates must inform the HCP that the question is off-label and they are not permitted to answer it. SKLSI Commercial Associates may offer to submit a Medical Information Request Form (MIRF) for the HCP.

SKLSI Policies *(continued)*

- **Gifts & Awards Policy** — Governs the provision or acceptance of gifts or awards by SKLSI Associates.
- **Prescription Drug Samples & Vouchers Policies** — Governs the disbursement of prescription drug samples and vouchers to HCPs.
- **Conflicts of Interest (COI) Policy** — Governs personal and professional COI that may affect the business judgment of SKLSI Associates and the interests of the Company.
- **Educational Grants, Donations, & Sponsorships Policy** — Governs the management, review, approval, or administration of Company contributions made in the form of financial, product, or in-kind support to US-based organizations such as professional, non-profit, and Healthcare Organizations (HCOs)

For more information concerning SKLSI policies and their relevant industry laws, regulations, and codes, refer to the Corporate Compliance Policies found on the SKLSI intranet.

Q: May I review a patient's medical records if an HCP provides them to me?

A: No, our *Patient & Patient Organization Interactions Policy* prohibits the unauthorized disclosure of patient Protected Health Information (PHI). Should you inadvertently encounter PHI during your job duties, refrain from further receiving or viewing it and prevent further unauthorized disclosure. Please also notify your manager of the situation right away.

Q: What should I do if a member of an HCP's office staff asks me to help complete missing information from a prior authorization form?

A: Politely inform the staff member that SKLSI policy prohibits you from completing any portion of a prior authorization. If they have any questions about how to correctly complete the form, you may connect them with the SK Navigator Team at 866-SKNAVIG (866-756-2844).

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Adverse Events and Product Complaints

- An Adverse Event is any new unfavorable or unintended sign, symptom, or disease, or change of an existing condition, which occurs during or after treatment with a drug or biologic product, whether or not it is considered drug-related
- All adverse events or Product Complaints, which include complaints regarding product quality and/or falsified products, that relate to a company product must be reported within 24 hours

All SKLSI Field Associates are responsible for reporting any safety or performance issues related to our marketed products, as well as investigational drugs in Clinical Trials.

Reportable events include, but are not limited to the following:

- Adverse event
- Lack of efficacy
- Maladministration/medication errors
- Drug abuse/misuse
- Accidental or inadvertent exposures
- Intentional exposure or overdose
- Drug-drug or drug-food interactions
- Suspected transmission of an infectious agent via a medical product
- Identification of a potential counterfeit medicine
- Exposure during pregnancy or lactation
- Product complaint (e.g., broken tablets, missing label)
- Side effects or adverse reactions that are mentioned in the product's package insert (PI)

Even if you are unsure if an event is an adverse event, you must report it.

Note: *Reporting an adverse event does not mean that the individual believes the report is true or that the reporter is committing SKLSI to accepting responsibility for causing an adverse event.*

Q: Is an adverse event most would consider positive, such as reducing cholesterol, considered an adverse event?

A: Yes. Even if the effect or symptom may be considered positive, the effect was unintended and therefore considered an adverse event.

Q: One of my HCP customers stated that they switched patients off of our product because it wasn't working for those patients. Do I need to report this?

A: Yes, you should report this to SKLSI for investigation.

Q: An HCP told me that our product didn't work on one of his patients. Do I need to report it?

A. Yes, lack of efficacy is considered an adverse event that must be reported to the Pharmacovigilance Department.

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How to Report an Adverse Event or Product Complaint

SKLSI Field Associates may receive reports of adverse events or product complaints from a variety of sources, including HCPs, patients, distributors, pharmacists, colleagues, social media, and friends. Adverse events or product complaints may be communicated during business activities such as informational or educational meetings, speaker programs, and conferences and congresses, or during social interactions. SKLSI Field Associates are required to report all adverse events or product complaints within 24 hours, regardless of:

- Who tells you about the event (HCP, patient, colleague, friend, etc.)
- How you found out about the event (word of mouth, email, standard mail, phone, fax, etc.)
- Whether the event is listed on the package insert
- Whether the event has been reported by another source

Adverse events and product complaints must be reported to SKLSI at 866-OKSKLSI (866-657-5574) or medicalinfo@SKLSI.com.

Information Required When Reporting

- Name of the SKLSI marketed drug
- Identified adverse event or product complaint
- Reporter contact information (e.g. Reporter name, phone number, email address)
- Patient identifiers, when available (e.g., patient initials, date of birth, age or age group, sex)

Note: *If a patient requests to remain anonymous, and patient identifiers are not provided, all adverse event or product complaint details should be forwarded as directed above.*

Q: What should I do if I overhear a Healthcare Professional (HCP) or patient describing an unintended effect of a company product?

A: You should contact the SKLSI toll free number and provide whatever information you have about the adverse event consistent with your training.

Q: What do I do if a patient or HCP requests that I not report an adverse event that they have experienced?

A: As an SKLSI Associate it is your responsibility to report all adverse events of which you become aware. In this circumstance you should report the adverse event as if the patient requested to remain anonymous—meaning you should report all required information except for the patient's identifying information.

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Communications with Healthcare Professionals

- Communications and interactions with Healthcare Professionals (HCPs) are intended to benefit patients and to enhance the practice of medicine
- SKLSI Field Associates must always provide HCPs with complete, truthful, and non-misleading information about our products
- SKLSI Field Sales Associate product communications must always remain consistent with the FDA-approved label

Promotional Communications with HCPs must:

- Only use materials approved by the Promotional Materials Review Committee (PMRC)
- Be consistent with the FDA-approved label
- Provide Fair Balance
- Target appropriate audiences
- Be truthful, accurate, and not misleading
- NOT discuss or make comparisons to competitor products or claims unless authorized by the PMRC Committee
- NOT market a product's profit potential to HCPs (sometimes referred to as "marketing the spread")

Communications with HCPs should be conducted via approved channels, such as SKLSI email, phone, or CRM communication methods. SKLSI Field Associates should avoid using personal accounts (e.g. personal email, social media) to communicate with HCPs.

Note: *A Package Insert (PI) must be offered during any promotional discussion.*

Appropriate Promotion

Promotional communications and product claims must be consistent with the product's FDA-approved label. This means you must:

- Only discuss disease states, patient populations, indications and uses, and dosages and administration consistent with the approved drug label
- Confirm a PI is included with promotional material left with an HCP
- NOT engage HCPs in "off-label" or unapproved product discussions
- NOT make inquiries likely to prompt off-label information in response

Off-label promotion means making claims that are inconsistent with the product's FDA-approved label or discussing unapproved uses of the product.

Q: What if an HCP asks me about an unapproved new drug, indication, or data from ongoing clinical studies?

A: You must indicate that this is not a topic you can discuss. You may reiterate the approved product indication and offer to submit the HCP's question via a MIRF to Medical Information for follow-up.

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If an HCP requests information that is not consistent with the approved product label, you must:

- Inform the HCP that the request is off-label and that you are unable to respond to the request
- Inform the HCP of the product's FDA-approved indication(s)
- Complete and submit a Medical Information Request Form (MIRF)

Note: *Medical will follow up with the HCP to provide an appropriate response to the request.*

Approved Materials

SKLSI Associates may use certain materials (printed, electronic, or other formats) to promote or educate HCPs about company products or disease states. SKLSI Associates must:

- Ensure that only PMRC-approved materials are used
- Confirm a PI is included with promotional material left with an HCP
- NOT photocopy, highlight, revise, alter, delete, or modify materials previously approved by the PMRC
- NOT distribute materials obtained from any source other than the PMRC (e.g., self-created materials from external websites, computer PIs, magazine articles, references to calculations of dose, cost comparisons)

Fair Balance

Promotional presentations, materials, and communications must always provide proper balance of product benefits and risks, known as "fair balance." This means you must:

- State all relevant safety information, warnings or precautions, side effects, and other pertinent information when providing product claims of safety and efficacy
- NOT emphasize positive data points only
- NOT take statements out of their original context or distort their meaning
- NOT present any side effect as if it were a benefit

Remember: *Informing HCPs about the benefits, risks, and appropriate use of our products can help advance appropriate patient care.*

Target Appropriate Audiences

Promotional communications must be directed to HCPs who are reasonably expected to prescribe or treat patients within the FDA-approved patient population. Targeting or promoting to HCPs who are not reasonably expected to treat patients within the FDA-approved patient population is prohibited.

Q: Do all electronic communications, such as an email to schedule a meeting with an HCP, need to be approved by the PMRC?

A: No. Using email to request or schedule meetings with an HCP does not need to be approved by the PMRC, provided you do not mention the product name in combination with any disease areas or indications for treatment in your communications with HCPs. The product name alone may be mentioned only for logistical purposes of scheduling a meeting. However, mentioning the product name and indication requires inclusion of product safety and risk information, which may not be fully captured in an email.

Remember, communications about SKLSI business should be conducted using approved communication channels (e.g., SKLSI email, phone). SKLSI Field Associates should avoid conducting business via personal accounts.

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Truthful and Not Misleading

You must never make any false or misleading claims regarding SKLSI products. A false or misleading claim is a statement that is not supported by adequate and well-controlled clinical studies or that fails to present all relevant data or context.

Competitor Products & Product Comparisons

- Only discuss or compare competitor products if they are included in PMRC-approved materials for use with HCPs, and after you have received training on how such materials may be used
- Do NOT engage in unapproved discussions of the comparative effectiveness or safety of a competitor's product, or even between different company products

Remember: *The FDA requires head-to-head clinical evidence to make any comparative claim. All comparative claims must be approved by the PMRC.*

Prescriber Data

Prescriber Data may be used by SKLSI for legitimate business purposes, including planning detailing and marketing activity, communicating important safety and risk information, and tracking and reporting adverse events related to SKLSI products. SKLSI complies with the guidance established by the American Medical Association (AMA) Physician Data Restriction Program to ensure responsible use of prescriber data.

SKLSI Field Associates may use prescriber data only as directed by the SKLSI Home Office. Prescriber data may not be shared or discussed with individuals outside of SKLSI, including HCPs in the call plan.

Field Associates may receive requests from HCPs to "opt out" of communications from SKLSI.

- For requests to opt out from SKLSI-specific data usage, communications, updates, and marketing activities, document the HCP's SKLSI opt-out request in the system
- For requests to opt out from data usage, communications, updates, and marketing activities for all companies (including SKLSI), advise the HCP to log on to the AMA website to submit an opt-out request

Questions related to the use of prescriber data should be directed to your manager.

Q: What do I do if an HCP asks me about a competitor's product?

A: If you have access to and have received training on PMRC-approved materials that discuss competitor products, you may discuss the PMRC-approved materials. If no PMRC-approved materials exist, or if you have not yet received training on their use, politely inform the HCP that you are not allowed to discuss competitor products.

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Vendor Credentialing and Institutional Access

Hospitals and other healthcare institutions where interactions with HCPs occur may require that SKLSI Field Associates complete vendor credentialing requirements before being permitted to access the facility. These are requirements initiated by the hospitals and institutions to gain access to their facility and cannot be waived by SKLSI. Generally, the purpose of these requirements is to ensure the ongoing safety of the institution's employees, patients, and customers, and the security of information that resides within the institution.

Information needed to comply with vendor credentialing requirements may include, but is not limited to:

- Immunization status (e.g., COVID-19 vaccination, flu shot, etc.)
- Copies of medical records demonstrating inoculation or immunity to certain illnesses
- Confirmation of a background check (and outcome)
- Training history
- Professional qualifications

SKLSI Field Associates are expected to comply with institutional credentialing requirements. SKLSI has engaged a third-party partner to support the vendor credentialing process for our employees. Requests for credentialing assistance should be directed to the SKLSI Credentialing Office at credentialing@sklsi.com or **888-231-5659.**

Data Privacy and Protected Health Information (PHI)

In your role in the Field, you may encounter PHI as a result of interactions with HCPs. PHI includes any information about health status, healthcare provisions, or payments for health care that can be linked to a specific individual. You should avoid situations where you may come into contact with PHI.

If you do come into contact with PHI, delete it. Then contact dataprivacy@sklsi.com for further guidance. Don't keep or share PHI that you inadvertently or accidentally come into contact with. For example, do not take photos of patient charts or take notes regarding any patient information.

There are a few exceptions to this guideline, which are detailed in our PHI and Data Privacy Policies. It may occasionally be necessary for you to obtain PHI as part of your role at SKLSI. For example, an HCP may disclose PHI to you in the case of an adverse event, and this must be reported appropriately. If you're ever unsure about your role with respect to PHI, contact dataprivacy@sklsi.com. Please make sure you don't include any PHI as part of your outreach to dataprivacy@sklsi.com.

Q: Where can I find more information on how SKLSI as a company handles PHI?

A: Read the PHI Policy and the Data Privacy Policy on the Intranet.

Q: What if I have questions about PHI and my responsibilities?

A: Reach out to the Data Privacy Office (dataprivacy@sklsi.com).

Q: What if I'm in an HCP's office and I accidentally receive patient personal data?

A: Do not keep it or share it. Contact dataprivacy@sklsi.com.

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Use of Promotional Materials

- All promotional materials must be reviewed and approved by the Promotional Materials Review Committee (PMRC)
- Promotional materials are intended to facilitate the safe, effective, and knowledgeable use of SKLSI's products consistent with the approved package insert
- Promotional materials must be used only for their intended, PMRC-approved purpose

General Requirements of Promotional Materials

- Only use promotional materials with the intended audience and in the manner approved by the PMRC without any changes
- Promotional materials may not be altered or modified in any way:
  - Includes highlighting, underlining, revising, summarizing, deleting, and copying
- Promptly destroy all promotional materials that are replaced or become outdated

Appropriate PMRC-approved Promotional Materials include (but are not limited to):

- Speaker Program slides (only for speaker meetings)
- Branded informational pamphlets
- Detail aids
- Materials describing SKLSI patient assistance programs
- Template electronic communications involving company products (e.g., emails and websites)

Note: *Promotional materials are developed and PMRC-approved for use with specific audiences and activities. All materials must be used only for the intended audience and/or activity. For example, patient materials should only be used with patient audiences and HCP materials should only be used with HCP audiences.*

Inappropriate Promotional Materials include (but are not limited to):

- Any item not approved by the PMRC
- Materials intended for internal educational purposes only
- Press releases
- Home-made promotional materials
- Photocopies of approved materials
- Expired or outdated materials
- Unauthorized electronic communications about a company product (i.e., posted through social media)

Q: If I run out of copies of a Promotional Reprint, can I download a copy of the reprint from the internet, print it, and distribute it to HCPs?

A: No. Copyright laws require that all Promotional Reprints be licensed and provided by the home office. This also prohibits photocopying or emailing PDFs of Promotional Reprints. SKLSI Associates who need additional reprints should contact Custom Point.

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Reprints

Reprints are copies of peer-reviewed scientific journal articles that provide scientific information or clinical data related to SKLSI products or disease states of interest to the company.

Reprints are reviewed and approved for distribution by SKLSI's Copy Review Committee (CRC); this review process may include:

- Outlining the rules for distribution in a Field Direction memo (or other means of instruction)
- Providing training to identify key points for discussion and sections that should not be discussed by Commercial Associates

Note: *Reprints must be distributed in accordance with the CRC-approved approach.*

Promotional Reprints

Promotional Reprints provide HCPs with current, relevant, and objective information about SKLSI products and related disease states. Reprints must be:

- Distributed only in the PMRC-approved manner
- Accompanied by the product's FDA-approved labeling, if the reprint relates to an FDA-approved product
- Documented in Veeva CRM to meet transparency reporting requirements

Note: *Reprints containing only disease education information that do not mention SKLSI products are distributed without an FDA-approved label.*

Distribution-Only / Sealed Reprints

Distribution-Only / Sealed Reprints are non-promotional, peer-reviewed scientific journal articles containing scientific information or clinical data related to SKLSI products where the content may reference content not consistent with the FDA-approved labeling.

Q: What do I do if an HCP attempts to discuss a distribution-only reprint?

A: Politely inform the HCP that you are not allowed to discuss the reprint but can complete a Medical Information Request Form for follow up.

Q: Why can I not attach a distribution-only reprint to my promotional materials?

A: Distribution-only reprints may contain information that is not consistent with the product label.. Combining a distribution-only reprint with promotional materials may imply that the product is approved for uses discussed in the distribution-only reprint. SKLSI Associates must provide these only in the manner approved by PMRC.

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Distribution-only reprints must:

- Provide truthful, accurate, and objective scientific information intended to educate HCPs, patients, and the public
- Be "left behind" and NOT discussed with the recipient
  - If a distribution-only reprint is left with an HCP on the same sales call as a promotional discussion, it should be dropped off at the end of the visit without discussing the topics or specifics of the article
- Be distributed as instructed by the PMRC (e.g., with shrink wrap intact and any stickers or disclaimers affixed)
- Be distributed separately from promotional materials and not "bundled" with promotional materials other than the FDA approved label if instructed by the PMRC
- NOT be provided or offered at promotional Exhibits or promotional speaker programs
- Documented in Veeva CRM to meet transparency reporting requirements

Note: *Questions related to the content of a sealed publication must be referred to Medical Information using the approved MIRF.*

Healthcare Economic Information (HEI)

Healthcare Economic Information (HEI) identifies, measures, or compares the economic costs of health outcomes with the use of one drug versus another, versus a different intervention, or versus no intervention.

HEI must be disseminated only to approved recipients (Formulary Committees, medical directors, healthcare economic experts, operations personnel of Managed Care Organizations (MCOs), payers, and similar HCOs) by trained SKLSI staff responsible for healthcare economics and outcomes research (HEOR). HEI must not be distributed as part of a normal product promotional detail.

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Samples and Vouchers

Samples and Vouchers:

- Are intended to enhance the practice of medicine, improve patient care, and provide cost savings for patients
- May NOT be provided to HCPs with the intent of influencing or rewarding them for purchasing, prescribing, or recommending SKLSI products
- May NOT be available for all patients, depending on their healthcare insurance and location

General Requirements

Samples and vouchers must:

- Only be provided to licensed HCPs in eligible states and territories who treat patients in the FDA-approved patient population and are reasonably expected to prescribe a SKLSI product for an approved indication(s)
  - The following states prohibit direct-to-practitioner shipments of controlled substances: Kentucky, New York, Rhode Island, and Vermont
- Be reviewed and approved by the PMRC prior to distribution or use
- Be tracked and reported in accordance with state and federal laws and company policies

Note: *SKLSI Associates must complete training on the policies and procedures related to samples and vouchers prior to distribution.*

Note: *SKLSI provides samples via direct shipment to HCPs. SKLSI Associates are not responsible for live distribution of samples.*

Samples and vouchers must NOT be:

- Sold, purchased, or traded
- Used for off-label product promotion
- Used as a discount, as free product (other than for a patient's trial use), to switch a patient from a competitive product, affect pricing (other than to lessen the co-pay to a patient), or to bypass government pricing or reporting requirements
- Provided to an HCP in exchange for new or additional prescriptions or a reward for past prescriptions
- Provided for personal use by HCPs, or use by friends or family members of SKLSI Associates or HCPs
- Used for clinical trials, research studies, or charitable donations
- Distributed to federal institutions (including their affiliated physicians)
- Distributed to pharmacies
- Distributed to prescribers at conventions or company-sponsored events

Note: *Each patient may receive a sample as an alternative to a voucher, but may not receive both a sample* ***and*** *a voucher.*

Q: How do I know if an HCP is eligible to receive samples or vouchers?

A: SKLSI's Sample Accountability and Voucher partners are responsible for confirming an HCP's eligibility to receive samples and vouchers. HCP Eligibility is noted in the HCP's account profile in Veeva.

Q: What do I do if a patient requests a voucher or sample from me while I am in a HCPs office?

A: Inform the patient that you are not allowed to provide vouchers or samples to patients and direct them to consult with their HCP.

Q: Can I share a voucher or sample with an HCP to influence them to switch patients over from a competitor product?

A: No. Vouchers and Samples are intended to provide support to patients who have been appropriately prescribed the product, not as an inducement to prescribe the product for a patient.

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Samples

A sample is a unit of drug not intended for sale. Samples are intended to allow patients to try an SKLSI product to determine if the product is an appropriate medical intervention at no cost, or to continue treatment during a short-term event until their prescription can be appropriately refilled as recommended by the patient's prescribing HCP.

- Samples may only be provided to HCPs, hospitals, or other healthcare entities that have the appropriate licenses and approvals to receive samples of an applicable product
- SKLSI Associates may submit sample requests from licensed HCPs
  - HCP eligibility to receive samples is confirmed by our Sample Accountability Vendor. If an HCP is found to be ineligible after a sample request is submitted, the SKLSI Associate who submitted the request is responsible for informing the HCP they are not eligible to receive the sample
- Valid sample requests are fulfilled directly by SKLSI's Sample Accountability Vendor
  - SKLSI Associates do not carry live samples and are not responsible for their distribution

SKLSI Sales Associates must submit Sample Order Requests only for authorized, licensed HCPs who treat eligible patients. Additional responsibilities include:

- Confirm the HCP is authorized to prescribe the medication and valid for sampling in Veeva
- Ensure that any state requirements are followed
- Adhere to the SKLSI sample allocation limits
- Witness and verify the HCP's signature
- Document requests according to SK's established business rules
- Submit all Sample Requests by end of each day
- Confirm the HCP completes the Acknowledgement of Content (AOC) and Acknowledgement of Delivery (AOD) upon receipt
- Immediately report any suspected misuse

SKLSI Associates must NOT:

- Remove samples from an HCP's office
- Handle or dispose of samples in any manner not directed by policy
- Damage, move, or dispose of competitors' samples
- Conduct return on investment (ROI) analysis on samples

Note: *SKLSI Associates must notify the Compliance Department immediately if there is evidence or a suspicion of any misuse or loss of a Sample (e.g., sale, billing, personal use) by an HCP or third party.*

Q: How do I ensure an eligible patient is receiving the sample?

A: You are responsible for ensuring the HCP understands that samples are intended for patients who are receiving a prescription for an on-label use of the product. The HCP is not required to provide information on which patients were provided samples, and you are not accountable for which patients the HCP selects to receive samples.

Q: If an HCP asks me to dispose of SKLSI samples, what should I do?

A: Inform the HCP that you are not allowed to remove samples from a HCP's office, then provide the HCP with the contact information of the SKLSI Sample Accountability Vendor.

Q: If the HCP is unable to meet with me to sign the Sample Request Form, can his/her administrative assistant collect the HCP's signature for me?

A: No. Samples are tightly regulated and you are required to witness the HCP's signature. For live/in-person interactions, you must be able to physically watch the HCP sign for samples (even if at a distance, e.g., from the hallway). For virtual interactions, you must request the HCP turn their camera on while signing the Sample Request Form.

Link to **Glossary** >>

Vouchers

Vouchers available to patients, either through website download or through HCPs, enable patients to obtain a trial of a newly prescribed medicine to determine if the prescribed medicine is an appropriate medical intervention.

Vouchers:

- Must only be distributed SKLSI Associates to HCPs or downloaded from the website
  - SKLSI Associates are not permitted to distribute Vouchers directly to patients, but may refer them to the website
- Must only be distributed to HCPs in a reasonable quantity
- Must be made available to all eligible HCP(s)
- May be requested by patients through the product website
- Must be distributed in their original form
  - SKLSI Associates may NOT alter, remove, apply stickers or labels, or cover any printed information

SKLSI Sales Associate responsibilities:

- Confirm the HCP is authorized to prescribe the medication and receive prescription drug vouchers, and treats the appropriate patient population
- Ensure that any state requirements are followed
- Ensure SKLSI voucher allocation limits are followed and vouchers are only distributed from your allocated supply
  - SKLSI voucher allocation limits: 10,000 vouchers or 2,000 voucher kits per rep per year
- Document voucher distribution according to SK's established business rules
- Provide vouchers only from your allocated supply
- Immediately report any suspected misuse

Q: Who is responsible for ensuring the patient is eligible to receive a voucher?

A: You are responsible for informing the HCP that vouchers are intended for patients who are receiving a prescription for an on-label use and have not previously used the product (either through a past prescription or a free sample). The HCP is responsible for providing vouchers to the patients or the patients can download directly.

Q: What should I do with expired vouchers?

A: Similar to promotional materials, you should return the expired vouchers to the appropriate SKLSI function for destruction. Contact Commercial Operations if you have questions.

Q: If I run out of vouchers, can I tell an HCP that they can download vouchers from the SKLSI website?

A: No. The vouchers on the website are only available for download by patients. However, you may inform HCPs that vouchers can be found online. Subsequently, HCPs may share that information with eligible patients.

Link to **Glossary** >>

Meals and Educational Items

SKLSI Field Associates:

- May provide modest and occasional Meals to HCPs as part of a bona fide business activity
- May NOT offer or provide anything of value to an HCP with the intent of influencing or rewarding them for purchasing, prescribing, or recommending a company product
- May provide HCPs with Educational Items that advance disease state or treatment education of HCPs or patients
- May NOT provide Gifts or entertainment to HCPs or patients
- Must accurately record all expenditures as part of transparency reporting

Meals

Meals must be:

- Part of an informational presentation or discussion
- Modest with regards to local standards
- Consumed during the business discussion (e.g., no "dine and dash")
- Held in a modest venue conducive to a business discussion
- Limited to an occasional basis, consistent with the call plan

Meal Guidelines

In-Office Meals

- Provided by Field Sales Associates on an occasional basis as part of an information presentation (no meal drops)
- Alcohol not permitted at in-office meals
- Meal expenses must be charged to "In-Office HCP Meals" in Concur and submitted with the associated sign-in sheet

Out-of-Office Meals

- Provided at speaker programs and business discussions related to SKLSI therapies, products, and relevant diseases
- Field Sales Associates and their immediate managers are not permitted to provide out-of-office meals to HCPs outside of speaker programs
- Meal expenses must be charged to the appropriate HCP meal type in Concur
- Reasonable alcohol consumption is permitted at out-of-office meals, provided that SKLSI Associates ensure they are presenting a professional image and not overindulging as a representative of SKLSI
- SKLSI Associates (including speakers) must not pay for or provide alcohol at speaker programs
- Entertainment and recreation are prohibited at business meetings

Note: *Area Executive Director-level roles and above (including Medical, Market Development Managers, Marketing, Sales Training, and Market Access) are permitted to provide occasional out-of-office meals to HCPs in connection with a business discussion and subject to the above rules.*

Note: *States may have limitations, prohibitions, and additional reporting requirements. Please refer to the section on Transparency Reporting.*

Q: Does providing a meal to an HCP with whom I have a personal relationship count as a business meal?

A: It depends. If you are providing the meal as part of a promotional or informational presentation, the meal counts as a business meal. If the meal occurs as part of your personal relationship outside of a promotional or information presentation, then the meal does not count as a business meal. In this case, the meal must be paid using your personal funds, must not include any discussion of SKLSI products or services, and cannot be submitted for reimbursement by the company.

Q: May Sales Associates meet an HCP for coffee off-campus or off-site?

A: No. Sales Associates may only provide food and beverage—even just coffee as in this scenario—during an informational discussion within the HCP's office. Sales Associates are not permitted to meet an HCP offsite for a meal or coffee.

Modest Meal Limits, Cost Per Person
(including meal, tax, gratuity, delivery)

Meal Type	In-Office	Out-of-Office
Breakfast		
Lunch		
Dinner		

Meals and Educational Items *(continued)*

Appropriate Attendees

- Licensed HCPs who provide treatment within the approved patient population
- Other appropriate targets such as pharmacists and APAs
- Relevant non-HCP office staff (in-office meals only)

Inappropriate Attendees

- HCP spouses or guests who do not independently qualify as an appropriate attendee
- HCPs unlikely to prescribe the product in accordance with FDA-approved labeling

Educational Items

Educational items must be:

- Approved by the PMRC
- Valued at a retail value of $100 or less and sourced by Marketing
- Unsolicited by HCPs

The distribution of educational items must be documented for reporting in accordance with federal and state reporting requirements.

Appropriate Educational Items

- Anatomical models for use in examination rooms
- Relevant Medical textbooks
- Relevant Medical journals or reprints

Inappropriate Educational Items

- Any item not PMRC-approved and/or not sourced by Marketing
- Any electronic device or other items that have value outside of HCP or patient education (e.g., a tablet or smartphone)
- Branded reminder items

Q: An HCP has asked to meet with me at the coffee shop located on the hospital campus to have a business discussion. Is this permitted?

A: Yes, Field Associates may meet an HCP in the coffee shop or cafeteria located within the hospital campus. Field Associates must ensure that the location is not off-campus and is conducive to a business discussion and is sufficiently private to ensure that the information provided during the discussion will not be exposed to potentially inappropriate audiences (e.g. patients, inappropriate specialties).

Link to **Glossary** >>

Prohibition on Gifts and Entertainment

SKLSI Associates are prohibited from providing gifts or entertainment of any type to HCPs.

Examples of prohibited forms of entertainment:

- Sports, theater, or other tickets
- Trips or vacations
- Rounds of golf

Examples of prohibited gifts:

- Gifts to acknowledge special occasions or holidays (e.g., gift baskets, candy, and flowers)
- Recreational electronic devices (e.g., DVD players and tablets)
- Branded reminder items (e.g., mugs, pens, and notepads)
- Cash or "cash equivalents" (e.g., gift cards and gift certificates)
- Sports equipment
- Bottles of wine or other alcohol

Additional Limitations for Meals and Items of Value

Several states, such as those referenced in this table, have implemented additional limitations on the provision of meals and other items of value to HCPs. For more information, refer to Transparency Reporting.

Additional Limitations for Items of Value		
State Limitations		
MN	Annually, max. $50/prescriber	Cumulative; applies to all Items of Value, including meals & educational items
NJ	Meal Limits: – $17/person, Breakfast & Lunch – $35/person, Dinner	– Limits apply to promotional interactions – Educational interactions exempt
VT	***Prohibits providing gifts, educational items, and meals to all HCPs licensed in Vermont, regardless of the event location or where HCP currently practices.***	
Limitations for Government Officials		
Government Official	Meal Limits: $20 per instance or $50 per year	

Q: Is it okay to give a food gift basket to an HCP's office in recognition of a special occasion if I pay for it personally?

A: No. Gifts to HCPs and their offices are not permitted under any circumstances. You are only permitted to provide PMRC-approved items related to HCP or patient education. Using personal funds to pay for other items does not change the policy requirement, as these items are considered to have value for the HCP unrelated to their professional activities. Please contact Compliance to discuss any questions.

Link to **Glossary** >>

Speaker Programs

- SKLSI engages HCPs to conduct promotional speaker programs designed to provide scientific and educational information on SKLSI products and relevant disease states
- Speakers may NOT be selected with the intent of influencing the speaker's use or purchase of an SKLSI product or as a reward for or in recognition of the speaker for purchasing, prescribing, or recommending an SKLSI product
- Speaker programs should address a bona fide educational need
- High-end restaurants, entertainment venues, or other similar venues are not appropriate locations for programs
- Repeat attendees at a program on the same topic will not be counted toward the minimum RSVP requirement for subsequent programs
- Friends, significant others, family, and other guests of speakers or invitees should not attend speaker programs unless they independently qualify as appropriate attendees

General Requirements

The purpose of speaker programs is to provide current information about SKLSI products and relevant disease states to members of the healthcare community. Speakers at these events are selected for their expertise in the subject matter of the program, and act as representatives of SKLSI. Speaker programs allow HCPs to hear an extended, on-label message about our products from one of their peers.

Speaker programs should be scheduled to accommodate a number of HCPs who have an educational need for the program content. Field Associates should try targeting the largest appropriate audience to attend the speaker programs to ensure the educational message is as effective as possible.

Speaker programs must:

- Follow the established brand plan
- Use content approved by the PMRC
- Be held in modest venues conducive to an educational presentation
- Be requested in advance of the desired date (e.g., 6 weeks for out-of-office; 4 weeks for in-office)
- Follow our company's HCP meal guidelines, including not providing or paying for alcohol
- Include a sign-in sheet identifying all attendees with printed names and signatures
- Meet RSVP requirements at least one (1) week before the program
  - In-office/virtual programs: 2 appropriate attendees
  - Out-of-office programs: 4 appropriate attendees
- Ensure that any colleagues of the speaker (e.g., members of same practice) do not make up the majority of attendees at the program
- NOT offer CMEs to attendees

Note: *Recording of speaker programs is generally prohibited. Requests for exceptions must be escalated to Legal.*

Q: May I ask a question of the speaker during the program?

A: No. SKLSI Field Associates may not prompt responses or otherwise direct a speaker during a program. The sole exception is if the speaker has communicated information that is factually incorrect or inconsistent with company speaker program policies.

Q: What do I do if a speaker violates SKLSI speaker program policies (e.g., skips safety slides or proactively discusses off-label information)?

A: Politely interrupt and request the speaker to review the skipped content or state that the information is not consistent with the FDA-approved label and cannot be discussed during the program. After the program, follow-up with your manager and report the occurrence to Marketing or Compliance.

Modest Meal Limits, Cost Per Person
(including meal, tax, gratuity, delivery)

Meal Type	In-Office	Out-of-Office
Breakfast		
Lunch		
Dinner		

Link to **Glossary** >>

Content must be:

- Presented in the PMRC-approved manner and not altered in any way (e.g., adding, removing, reordering, or skipping content)
- Consistent with the FDA-approved labelling, accurate, and fair-balanced (i.e., ensure appropriate time is being given to any slides addressing product safety to ensure fair balance)
- Free of comparative or superiority claims regarding other competitors' products, unless PMRC-approved
- Clearly identified as an SKLSI presentation

Note: *PIs must be made available to all attendees at product-focused speaker programs. PIs and other product-focused promotional materials may NOT be distributed at disease education speaker programs.*

Venues must be:

- Modest and not affiliated with entertainment
- Conducive to an educational program or business meeting
  - Venues such as luxury hotels, high-end restaurants, spas, resorts, amusement parks, museums, or country clubs are not appropriate (no bars or entertainment venues)

Note: *The SKLSI speaker portal contains pre-approved program venues.*

Attendee Confirmation:

- If a speaker program does not meet the minimum RSVP requirement one (1) week before the date of the speaker program, the program must be canceled
  - For in-office or virtual programs, a minimum of 2 confirmed appropriate attendees are required
  - For out-of-office programs, a minimum of 4 confirmed appropriate attendees are required
- Speaker colleagues (e.g., members of same practice) do NOT count toward the minimum attendee requirement

Note: *In the event that a speaker program meets the confirmed RSVP requirement but less than the minimum required attendees arrive and participate in the event, the speaker program may continue as scheduled. This exception must be communicated via a Speaker Program Exception/Deviation Disclosure Form submitted to Compliance within 48 hours of the event conclusion.*

Q: What should I do if my program had the appropriate number of RSVPs, but they did not all show up for the program?

A: You may proceed with the program as normal but inform your manager and Marketing or Compliance within 48 hours that the confirmed minimum number of attendees did not show up for the meeting.

Link to **Glossary** >>

Responding to Unsolicited Off-Label Questions

If an attendee asks an unsolicited off-label question, the speaker may:

- Respond to the question based on their own clinical experience, or
- Refer the attendee to the SKLSI Sales Associate, who may assist them in submitting an SKLSI Medical Information Request Form (MIRF)

Speaker responses to unsolicited off-label questions must:

- Be identified as off-label,
- Be narrowly tailored to the specifics of the request
- Return to the approved presentation immediately after providing a response.

If the attendee has additional questions related to the off-label discussion, the speaker must defer the discussion until after the presentation has concluded. The speaker may then find an appropriate area to have a 1:1 discussion with the attendee.

Speaker Program Attendees

Appropriate attendees include:

- HCPs who are reasonably expected to prescribe or treat patients within the FDA-approved patient population
- Clinical support staff with a role in providing patient care (e.g., Pharmacist, RN, MA)

Note: *Office Managers may attend with their affiliated HCP.*

Inappropriate attendees include:

- Spouses, partners, family members, or other guests who do not independently qualify as appropriate attendees on their own
- HCPs in unapproved or excluded specialties

Attendees must not be paid for time, travel, accommodations, or other reimbursements (e.g., parking, tolls).

Although an HCP may attend programs on the same topic more than once, remember that after the first program on the topic:

- Attendees are not eligible to receive a meal
- Attendees are not counted toward the minimum attendance requirement

Q: What should I do if an attendee who did not RSVP shows up to the program?

A: Introduce yourself to the HCP, confirm his or her credentials (e.g., approved specialty), and request the HCP to print their name and sign the program sign-in sheet like other invited attendees.

Link to **Glossary** >>

A program is considered the same based on the content (e.g., slide deck) presented.

A program is considered different only if there are substantive changes to the relevant information included in the speaker deck.

Note: *SKLSI speakers are not permitted to attend speaker programs on topics similar to the one on which they are trained to present. Exceptions must be approved by Compliance and Marketing.*

At least one SKLSI Associate must attend each program and ensure adherence to the Compliance Manual and Speaker Program Management Best Practices. SKLSI Associates attending speaker programs must:

- Provide attendees with the applicable Package Insert(s) for each product discussed
- Complete all required documentation (e.g., sign-in sheet, receipt entry)
- Promptly report potential violations to his or her manager, Marketing, and Compliance

Note: *SKLSI Sales Associates must not proactively invite MSLs to promotional speaker programs. MSLs may choose to attend a program on their own.*

Program Exceptions and Deviations

SKLSI Compliance has created a Speaker Program Exception/Deviation Form to assist in resolving any exceptions to or deviations from the guidance provided in this Field Guide. SKLSI program hosts should submit a completed Speaker Program Exception/Deviation Disclosure Form to Compliance and Marketing if:

- During the program planning phase, the host identifies a need to request an exception from the established program requirements (e.g., obtain approval for a new venue)
- After a program has concluded, the host identifies those aspects of a program that may have deviated from the guidance provided in this Field Guide (e.g. inappropriate attendee, a late arrival misses the presentation)

Conducting Speaker Programs

All speaker programs must be scheduled and administered through the SKLSI speaker portal. Only speakers who are part of the approved speaker bureau may be requested.

The following information must be entered into the portal to schedule a speaker program:

- Name of speaker
- Speaker program title
- Speaker program location
- Date of program

Q: What constitutes a "substantive change" to the speaker deck?

A: Changes to the speaker deck that may qualify as "substantive" include:

- A new or expanded FDA-approved indication for the product
- Significant update to clinical data (e.g., the publication of long term safety data)
- Changes to the administration or dosing methodology
- Changes to the management of Adverse Reactions

If you are uncertain whether updated information qualifies as "substantive," consult the Marketing team for clarification.

Q: An attendee has offered to open a bar tab at the program's venue on behalf of other attendees. Is this permitted?

A: SKLSI does not purchase or provide alcohol at speaker program events. However, if attendees wish to purchase their own alcohol to consume with a speaker program meal, they may do so, in accordance with venue and local restrictions.

Speakers must not pay for or provide alcohol for others. SKLSI does not reimburse for alcohol consumed at a speaker program.

Link to **Glossary** >>

Speaker Program Meal Expenses

Speaker program meal expenses are paid directly by the SKLSI speaker bureau. Sales Associates are prohibited from paying for any program meal expenses unless otherwise approved by Marketing or Compliance.

Note: *SKLSI does not pay for or provide alcohol at speaker programs.*

Post Program Close-Out Requirements

After the program, the SKLSI Associate hosting the program must submit program close-out documents (including receipt and sign in sheet) to the speaker program vendor. The vendor will review the documentation and approve closure of program.

Speaker Selection & Criteria

Speakers are selected based solely on their professional knowledge and experience as an HCP in the relevant disease area and capability as a promotional speaker for SKLSI. Field Sales teams may refer unsolicited requests from HCPs who wish to become speakers to the SKLSI Speaker Selection Committee, but may not proactively nominate speakers or negotiate, make assurances, or enter into contracts with HCPs.

Speaker Utilization

Speakers should be utilized based on an existing need to educate the HCP audience. Our policies require speakers to conduct a minimum of two speaker programs in a twelve-month period to be considered eligible for speaker bureau renewal.

Note: *Speakers that conduct two programs within the same day are considered to have met the eligibility requirement.*

Transparency and Reporting

SKLSI Associates must submit accurately completed sign-in sheets and itemized receipts in the speaker program portal in order for the speaker bureau to capture and report all transfers of value.

Link to **Glossary** >>

Speaker Program Checklist

SK life science
a subsidiary of SK biopharmaceuticals

Partner with Compliance

BEFORE THE SPEAKER PROGRAM

Planning

- ☐ Program must provide an educational benefit
- ☐ Program is entered through speaker bureau portal
- ☐ Location selected is conducive to an educational presentation
- ☐ Employees do not arrange for or provide attendee transportation or parking expenses
- ☐ Employees may coordinate with the Speaker Program vendor to ensure appropriate speaker transportation arrangements
- ☐ Download approved invitation template from speaker bureau portal
- ☐ Enter all HCP invitees in speaker bureau portal
- ☐ Complete the Speaker Program Exception/Deviation Disclosure Form (if applicable)

Speaker & Attendees

- ☐ The speaker is from the approved speaker list
- ☐ Attendees invited are from the appropriate target audience
- ☐ Host responsible for Speaker Program will be in attendance
- ☐ SKLSI attendees do not outnumber HCP attendees

DURING THE SPEAKER PROGRAM

SKLSI Field Associate Responsibilities

- ☐ Introducing the speaker
- ☐ Distributing or offering the approved Package Insert (PI) and approved promotional materials or PMRC-approved disease education materials
- ☐ Ensuring the speaker utilizes the appropriate, approved speaker slide deck
- ☐ Monitoring Speaker Program meal costs for compliance
- ☐ Circulating sign-in sheets, ensuring they contain complete information for each attendee, and appropriately closing the Speaker Program
- ☐ Reporting any compliance issues or potential violations to your manager, Marketing, Legal, or Compliance within 48 hours

Attendees

- ☐ Out-of-Office Programs: At least 4 appropriate attendees of the appropriate target audience (excluding speaker) are present
- ☐ Out-of-Office Programs: Members of the same practice as the speaker do not make up the majority of attendees at the program
- ☐ In-Office/Virtual Programs: At least 2 appropriate attendees of the appropriate target audience (excluding speaker) are present
- ☐ All attendees complete the approved sign-in sheet (including signatures)
- ☐ All attendees are appropriate (no spouses, office staff, etc.)

Materials

- ☐ All materials are PMRC-approved and used in the approved manner
- ☐ Package Insert (PI) is made available during the product presentation

Meals and Entertainment

- ☐ Meal provided (if any) is modest and within company meal guidelines
- ☐ Entertainment or gifts are not provided

SKLSI does not pay for or provide alcohol.

Speaker

- ☐ Speaker uses and follows the approved presentation

If speaker receives unsolicited off-label questions:

- ☐ Speaker advises the answer is outside of approved labeling and provides a narrow response to the person who asked the question and refers the question to Medical for follow-up
- ☐ If requested, the Speaker Program host documents the question in a Medical Information Request Form (MIRF)

Speaker does not:

- ☐ Use any unapproved materials or messaging
- ☐ Prompt or encourage off-label questions
- ☐ Discuss any specific patients without prior PMRC approval
- ☐ Discuss unapproved reimbursement, insurance, or pricing information

AFTER THE SPEAKER PROGRAM

Documentation Follow-up

- ☐ Provide any off-label information requests to Medical Information
- ☐ Complete all required documentation or messaging
- ☐ Complete the Speaker Program Exception/Deviation Disclosure Form (if applicable)

Systems Follow-up

- ☐ Enter all required meeting information in the speaker bureau portal
- ☐ Provide all expense information to the Speaker Program portal or enter in Concur if required

Grants, Charitable Donations, & Sponsorships

- SKLSI funds may never be offered or provided with the intent of influencing or rewarding for purchasing, prescribing, or recommending an SKLSI product
- The Grant Review Committee is responsible for oversight and approval of all grants
- All local exhibit, health fair, and Sponsorship requests require an approval by a Regional Sales Director (RSD) and Compliance
- All distributed product promotional materials must be approved by PMRC

EDUCATIONAL GRANTS

SKLSI supports medical education programs, including accredited, non-accredited, and patient education programs. The grants process is managed by the Grant Review Committee and is separate from Commercial involvement. SKLSI Field Associates should refer all HCPs and customers to direct their grant requests and questions to grants@sklsi.com.

Grants may NOT be awarded to individual physicians, physician groups, health plans, or managed care organizations.

SKLSI Field Associates may NOT:

- Solicit or discuss educational grant requests with HCPs or customers
- Respond to questions about grants beyond providing the Grant Review Committee contact information
- Help fill out grant proposal forms, guarantee approval, or provide direction or advice about a grant request

RESEARCH GRANTS AND INVESTIGATOR INITIATED STUDIES (IISs)

SKLSI may support clinical trials, healthcare economic, or outcomes research conducted by external investigators related to an SKLSI product or therapeutic area of interest to the company through the provision of research grants or Investigator Initiated Studies (IISs). Research grant and IIS requests are managed through our Medical Affairs function.

All questions regarding the availability or status of IIS funding requests must be directed to Medical Information.

SKLSI Field Associates may not:

- Assist in the development of an IIS
- Guarantee the funding of an IIS

Link to **Glossary** >>

CHARITABLE DONATIONS

SKLSI may provide Charitable Donations at a corporate level to local chapters of non-profit, 501(c)(3) charitable organizations whose goals align with SKLSI's focus of patient healthcare, education, and advocacy. The types of activities the company supports at a corporate level include walks, runs, charitable dinners, and similar fundraising activities, for which SKLSI does not receive a direct or tangible benefit (e.g., a booth or display table).

Requests for charitable donations must be submitted for approval to donations@sklsi.com.

SKLSI Field Associates cannot fund charitable events and cannot provide HCPs with tickets to attend such events; purchasing tickets to attend such events using your company expense card is not allowed. However, SKLSI Field Associates may attend events such as health fairs, dinner galas, or "fun runs" on behalf of SKLSI, if approved by your manager and in coordination with patient advocacy and consistent with all policies and guidelines. However, you must not discuss SKLSI products at such events except in association with a company-approved promotional exhibit request.

SPONSORSHIPS

SKLSI may provide funding in the form of "sponsorships" to organizations whose goals align with SKLSI's focus of HCP and patient healthcare, education, and advocacy SKLSI will typically receive a tangible benefit (e.g., an exhibit booth or logo placement) as part of sponsorship funding. Sponsorships may include:

- Non-CME scientific & medical congresses, conferences, conventions, and symposia in therapeutic areas where SKLSI has an approved product or is conducting research
- Regional or local medical societies dedicated to therapeutic areas consistent with SKLIS's product label
- Promotional or disease education exhibits and displays at local conferences, hospitals, and medical centers
- Community health fairs and advocacy events (e.g., walks, runs, charitable dinners, and other fundraising activities)
- Society and association meetings, receptions, dinners, and breaks (meal sponsorships at such events must be in compliance with SKLSI's guidance for meals provided to HCPs)
- Patient/caregiver education programs

Q: An HCP in my call universe asked about whether there was an opportunity to submit an idea for research involving our product. May I direct her to the local Medical Science Liaison (MSL)?

A: Yes. Requests for IIS must be directed to Medical Affairs, and it is appropriate to complete a Medical Information Request Form (MIRF) so an MSL can help explain the overall SKLSI IIS process.

Link to **Glossary** >>

General Requirements for Sponsorships

Sponsorship BNA requests should:

- Have a legitimate business purpose related to SKLSI's approved product indications
- Be accompanied by a written request from the organizer on the organization's letterhead
- State whether SKLSI will be sole sponsor or others have been solicited
- Specify the amount of funding requested and describe how the funding will be used
- Provide the date and location of the planned event
- Describe the tangible benefit provided to SKLSI if funding is approved
- Be for events that are held at modest venues and do not include entertainment
- Indicate the expected number and specialty of attendees
- Include an event program or agenda brochure
- Include IRS Form W-9
- Include ACH information if available
- Be submitted at least 30 days prior to the event or payment due date

Other sponsorship requirements include:

- Sponsorship fees must be based upon Fair Market Value (FMV) of the tangible benefits provided
- All distributed materials must be PMRC-approved
- All patient education and support items (e.g., patient disease materials, water bottles, blankets)
- Must be PMRC-approved for distribution to patients
- Modest refreshments may be offered to HCP and patient attendees as part of SKLSI's exhibit activities
  - Such refreshments are not reportable under Federal Sunshine Act provided they are made available to all event participants

All sponsorship requests require Compliance review and approval.

- Manual submission (KAMs, Marketing):
  - SKLSI Field Associates must complete the Sponsorship BNA with assistance from the Market Development Manager (MDM), if applicable
  - Associates submit the finalized BNA to the supervisors for approval
  - Supervisors submit the approved BNA to Compliance at sponsorshiprequests@sklsi.com

Q: As part of an approved sponsorship of an event, SKLSI received eight tickets to a gala. May I invite an HCP from my territory to join our table?

A: No, tickets may not be provided to HCPs or their supporting staff. However, SKLSI Associates may be permitted to attend. You should discuss appropriate attendance with your manager. In the event there are unused tickets, they should be offered back to the organization.

Link to **Glossary** >>

- Web Application Submission (NAMs, MDMs):
  - SKLSI Field Associates must confirm with RSD and complete the sponsorship BNA using the BNA Web Application
  - Associates should submit the finalized BNA. It will be reviewed and approved or denied by the Market Development Manager, Area Executive Director, and Compliance
  - If approved, the system will send confirmation of approval (and supporting documentation) to the original Requester, Approver, and Marketing Center Assistant

Exhibit Requirements

When included as part of an approved sponsorship, SKLSI Field Associates may staff an exhibit booth at events such as conferences, conventions, and health fairs.

When attending such events, SKLSI Associates must abide by the following guidelines:

- Field Sales Associates may staff only Commercial booths, and must not participate in any activity at Medical booths
- All materials and messaging shared at such events must be PMRC-approved
  - Exhibit display materials (e.g., tablecloth, posters, etc.) must also be PMRC-approved
- Requests for information about an unapproved use of SKLSI products must be referred to the Medical booth, or submitted via a MIRF
- SKLSI must not pay for or provide alcohol at these events.

For promotional events where the primary audience is composed of HCPs (e.g., scientific or professional conferences):

- Booth materials may include use of SKLSI product logos
- PMRC-approved promotional materials related to SKLSI products may be distributed
- Sponsorship funding may be used by the event organizer to provide modest meals to attendees
- SKLSI Field Associates may provide nominal snacks at the event booth (e.g., water, pretzels)
- SKLSI Field Associates must not purchase meals for event attendees

For events where the audience includes patients and caregivers (e.g., health fairs, patient educational conferences):

- Booth materials must be limited to SKLSI corporate branding
  - Use of product-specific logos, colors, and information is prohibited
- All patient education and support items (e.g., patient disease materials, water bottles, blankets) must be PMRC-approved for distribution to patients.
- Sponsorship funding may be used by the event organizer to provide modest meals to attendees
- SKLSI Field Associates may provide nominal snacks at the event booth (e.g., water, pretzels)
- SKLSI Field Associates must not purchase meals for event attendees

Q: Is it okay for me to set up a promotional display or exhibit at a local conference with continuing medical education (CME) programs?

A: Yes, if permitted by the conference. You should first consult with the conference organizer for specific requirements, but SKLSI policies allow for promotional displays or exhibits at CME events so long as the display or exhibit and accompanying promotional activities are conducted separate and apart from the CME space.

Link to **Glossary** >>

Interactions with Patients and Patient Organizations

Partner with Compliance

- Interactions with patients and Patient Organizations are intended to support the shared mission of understanding by addressing the needs of patients
- SKLSI respects the values and independence of patient organizations and the patient-HCP relationship
- All topics and materials used during patient or patient organization engagements must be PMRC-approved
- SKLSI Field Associates must respect the privacy of patients' PHI
- SKLSI Associates must not discuss patient-specific treatment plans, and refer all patient-specific questions back to the treating HCP

INTERACTIONS WITH PATIENTS

Clinical and Hospital Interactions

When in an HCP office, hospital, or other medical treatment facility, SKLSI Field Associates may not engage patients or their Caregivers. SKLSI Field Associates may not provide patient education materials, even if requested by a patient or caregiver. Redirect the patient or caregiver to his or her HCP. SKLSI Field Associates must:

- NOT participate in or be present during an HCP's consultation with a patient
- NOT engage in product-related or treatment discussions with patients or caregivers

Patient Conferences

Conferences and health fairs are intended to provide patients with information about disease states and potential treatment options. Where appropriate, SKLSI Field Associates may submit requests for support via the sponsorship request process, provided the event aligns to the principles outlined in the Sponsorships section of this manual (e.g., aligned to a legitimate business need, sponsorship fees based on FMV, held in a modest venue, etc.).

When approved by their manager, SKLSI Field Associates may attend Patient Conferences and health fairs. At patient conferences and health fairs, SKLSI Field Associates may:

- Staff SKLSI booths at the conferences
- Engage in discussions that the company has approved for patient audiences
- Provide PMRC-approved patient education materials at a booth or exhibit and request patients or caregivers to follow up with their HCP for more information
- Provide modest snacks to event attendees as part of SKLSI's overall sponsorship and support
- NOT engage in interactions related to patient-specific treatment plans

Q: If a patient or caregiver starts talking to me while I am in an HCP's waiting room, how may I respond?

A: You may respond by politely introducing yourself and engaging in cordial conversation. You may NOT discuss company products, treatment options, or other medical topics with the patient or caregiver.

Link to **Glossary** >>

Patient Support Group Meetings

Patient support groups enable patients to connect with others who share similar disease experiences with the goal of providing education, emotional support, and access to resources for disease management. SKLSI Field Associates may attend patient support group meetings to provide patient support materials and a modest meal. At patient support group meetings, SKLSI Field Associates may:

- Provide PMRC-approved patient education or support materials
- Provide occasional meals not exceeding $35 per meal participant
- NOT promote SKLSI products or discuss medical or treatment questions with patients and caregivers

Note: *SKLSI Field Associates attending patient support group meetings may attend only as silent observers; engaging in discussion about SKLSI products, relevant disease states, or patient-specific information is prohibited.*

SKLSI Field Associates may provide patient support groups with HCP speakers for non-promotional presentations focusing on disease state education or other patient health and wellness topics. Such patient-focused speaker programs must be organized through the SKLSI speaker bureau portal.

Patient support group speakers must:

- Be contracted and approved prior to speaking
- Only use PMRC-approved materials intended for use with patients
- NOT alter the approved presentation in any way

An SKLSI Field Associate may be in attendance for the duration of the presentation in order to monitor for speaker compliance. SKLSI product package inserts and promotional materials may NOT be distributed at patient-focused speaker programs.

Patient Advocacy Events

Requests for support for patient advocacy events must be submitted via the established Sponsorship request process. SKLSI Field Associates may attend events such as health fairs, dinner galas, or "fun runs" on behalf of the company, if approved by their manager. SKLSI Field Associates may not promote company products at patient events. All patient education and support items (e.g., patient disease materials, water bottles, blankets) must be approved by both the PMRC and Compliance for distribution to patients. Modest meals may be offered to attendees as part of SKLSI's sponsorship and support.

Q: One of the HCPs in my area requested that SKLSI sponsor their annual offsite for team building and staff development. How should I respond?

A: Politely inform the HCP that SKLSI policy only allows for sponsorships that focus on HCP and patient education and advocacy. SKLSI does not sponsor events that are for the personal benefit, staff development, and/or entertainment of HCPs.

Link to **Glossary** >>

Patient Privacy

SKLSI Field Associates must avoid situations in which they may be exposed to a patient's PHI. In the event that a patient's PHI is inadvertently disclosed, SKLSI Field Associates must ensure that the information is not utilized, shared, or distributed.

If you encounter PHI:

>> In an HCP office:

- Do not document patient information that you may hear in an HCP office
- Do not request or attempt to access patient charts
- Do not accept documents that contain patient information

>> Via email:

- Alert the sender you do not have a business need to receive PHI and you will delete the information from your email
- Delete the email containing PHI from your inbox, then delete it from your Trash folder
- Do not forward the email to any other recipients

>> At a patient conference, support group meeting, or advocacy event:

- Do not document patient information that you may hear at these events
- Do not solicit information from patients
- Do not accept documents that contain patient information

Link to **Glossary** >>

INTERACTIONS WITH PATIENT ORGANIZATIONS

Interactions and relationships with patient advocacy groups and other patient organizations may include direct financial support as well as indirect support (e.g., providing time of an agency for the patient organization to use).

All interactions must:

- Be transparent and adhere to high ethical standards
- Have a legitimate business need consistent with the mission of the organization
- Be tailored to the specific patient organization
- Not interfere, or appear to interfere, with the independence of the organization
- Be held in a modest venue conducive to informational exchange
- Be free of entertainment or recreation
- Be supported by written documentation
  - A formal contract between the patient organization and SKLSI may be required, depending upon the nature of support provided
- Ensure any Fee-for-Service (FFS) engagement complies with the requirements outlined in the Fee-for-Service Policy and is based on FMV

Note: *SKLSI may not request or require to be the sole funder of a patient organization or event. If an organization is unable to obtain additional funders, Compliance must be notified prior to the event for additional review.*

Appropriate interactions with a patient organization or its representatives include:

- Providing education about SKLSI products, relevant disease states, and SKLSI programs for patient support and product access
- Attending or providing support for a patient advocacy event, such as an education meeting, health fair, or dinner gala
- Leaving PMRC-approved patient education or support materials on the table for patients to take at patient advocacy events or patient conferences

Inappropriate interactions include:

- Engaging in patient-specific discussions related to treatment
- Inviting representatives of a patient organization to a promotional speaker program designed for HCPs
- Directing the patient organization to send product-related material to its members or otherwise promote any products to their members or the public
- Making sponsorship or funding decisions based on an organization's endorsement activities of a product or company
- Modifying patient organization materials in a way that is favorable or unfavorable to a particular treatment (even if SKLSI is sponsoring the materials)
- Ask a patient organization to endorse SKLSI or any of its products

Link to **Glossary** >>

Transparency Reporting Laws

- SKLSI is committed to conducting business in a transparent and ethical manner and in accordance with all federal and state legal requirements
- SKLSI Field Associates must track all transfers of value and payments to HCPs and HCOs
- It is your responsibility to use a sign-in sheet when appropriate, enter your expenses on time, and assist with remediation activities, as applicable to ensure the most accurate data possible

TRANSPARENCY REPORTING

US federal and several state governments have enacted laws, such as the Sunshine Act, to bring increased transparency to interactions between pharmaceutical manufacturers and HCPs and HCOs.

Federal Law

The Sunshine Act requires manufacturers to report to the federal government certain general and research transfers of value made to certain HCPs and Teaching Hospitals. These transfers of value are made publicly available on the CMS website. SKLSI relies on its employees to perform their obligations to collect accurate, complete, and timely data.

Tracking

The company must record and report transfers of value or payments to physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse midwives, and teaching hospitals, including but not limited to:

- Meals
- Educational Items for HCPs (e.g., reprints and textbooks)
- Compensation for services (e.g., consulting fees and speaker fees)
- Travel and lodging
- Research funding or grants
- Charitable Donations

For each reportable transfer of value or payment we are required to disclose:

- The amount of the payment
- The date the payment occurred
- The Form of the payment (e.g., cash equivalent or in-kind items)
- The Nature of the payment (e.g., consulting fees, travel, or food)

Q: Why does the company need to track all transfers of value to HCPs?

A: The Sunshine Act and some state laws require drug manufacturers to disclose transfers of value to Covered Recipients for publication on the Internet. Therefore, your tracking of transfers of value in the applicable system is a critical step in our reporting process.

Q: What should I do if an HCP approaches me with a question or concern about information SKLSI has reported about him or her?

A: Please contact Compliance right away and do not work to investigate or resolve the matter on your own.

Link to **Glossary** >>

- For HCP payments:
  - The HCP's full name, business address, Specialty, National Provider Identifier (NPI), and State License Number (SLN)
- For teaching hospital payments:
  - The teaching hospital's name, business address, and tax ID number (TIN)

Certain exceptions exist for transfers of value that do not need to be reported. However, it is not your responsibility to determine whether a transfer of value is reportable; Compliance will make this determination when submitting the reports. If you have a question about whether a transfer of value or payment is reportable, you should capture it then follow up with your manager or Compliance to discuss further.

STATE AND LOCAL LAWS

Certain states and other localities have enacted laws in addition to the Sunshine Act regulating interactions with HCPs and HCOs. State laws may include requiring disclosures on a broader range of HCPs (e.g., nurses or pharmacists) or providing limitations or prohibitions on the types of allowable interactions. At SKLSI, the following are considered HCPs for transfer of value tracking purposes: physicians, physician assistants, nurse practitioners, nurses (all types), pharmacists, formulary committee members, and clinical trial investigators.

Below is a list of state and local regulations current as of the publication of this Compliance Manual. Note that this list is non-exhaustive, as local legislation changes frequently. Please contact SKLSI Compliance for the most up-to-date information about state and local requirements. SKLSI Compliance will work with Field Associates to ensure field activity is conducted and documented in compliance with established regulations.

Q: What should I do if an HCP asks me what value will be reported for a meal or a transfer of value?

A: All questions related to the reported value must be escalated to Compliance.

When it comes to educational materials—such as certain scientific journal articles that have been approved for dissemination—the exact transfer of value amount will be known and will need to be disclosed to the HCP at the time the transfer of value is provided. For all other transfers of value, the amount is not known until the data is being aggregated for reporting to the government. In that instance, the transfer of value amount is available during the Sunshine Act data review and dispute period.

Link to **Glossary** >>

Transparency Reporting Laws *(continued)*

STATE LAWS		
CA	**Limitation:** Manufacturers are required to establish specific annual per physician dollar limits on gifts, promotional materials, and activities provided to HCPs. SKLSI has established a threshold of $2,500 per year per covered recipient.	
CT	**Limitation:** SKLSI Field Sales Associates must not provide gifts to state government employees unless they are valued at $10 or less and the aggregate value of all items provided does not exceed $50 in a calendar year. Food and beverages provided to state government employees must not exceed $50 in aggregate value in a calendar year.	**Pharmaceutical Detailer Licensure and Registration:** Manufacturers that spend more than $3,000/year on lobbying activities must register as a Client Lobbyist, and SKLSI Associates that call on P&T Committee members in an effort to have a drug placed on the state's preferred drug list may be considered a Communicator Lobbyist. Anyone considered a Communicator Lobbyist must register and provide quarterly reports.
District of Columbia	**Aggregate Spend Disclosure Report:** Manufacturers and labelers of prescription drugs who engage in marketing in the District of Columbia are required to report their marketing and advertising costs.	**Pharmaceutical Detailer Licensure and Registration:** Pharmaceutical representatives practicing "pharmaceutical detailing" in the District of Columbia must be licensed.
KY	**Limitation:** SKLSI Associates must not provide any gift or meal valued at more than $25 to any state government employee, their spouses, or dependent children.	**Pharmaceutical Detailer Licensure and Registration:** Pharmaceutical employees whose position involves attempting to influence members of the P&T Advisory Committee must register as executive agency lobbyists.
LA	**Limitation:** SKLSI Associates must not provide any gift or meal valued at more than $50 to any state government employee, their spouses, or dependent children.	**Pharmaceutical Detailer Licensure and Registration:** Pharmaceutical employees whose position involves engaging members of the P&T Committee for the purposes of inclusion of a product on the Medicaid formulary must register as lobbyists.
MA	**Aggregate Spend Disclosure Report:** Manufacturers must disclose the value, nature, and purpose of economic benefits with a value of at least $50 provided directly or indirectly to any covered recipient in connection with a company's sales and marketing activities.	**Prohibition:** Massachusetts prohibits meals offered, consumed, or provided outside of an HCP's office or hospital setting. The lone exception is meals offered as part of a non-CME educational presentation.
MN	**Aggregate Spend Disclosure Report:** Manufacturers are required to report all honoraria and payments to HCPs serving as speakers at professional or educational meetings and compensation for substantial professional or consulting services of HCPs working on research projects totaling $100 or more.	**Limitation:** Minnesota prohibits providing gifts and promotional meals with a combined value greater than $50 to an individual physician in a calendar year.
NV	**Aggregate Spend Disclosure Report:** Manufacturers are required to report a list of all individuals to whom they provided any type of compensation over $10 or aggregate compensation over $100 during the previous calendar year.	**Pharmaceutical Detailer Licensure and Registration:** Manufacturers must submit to the Nevada Department of Health and Human Services a list of all pharmaceutical representatives that spend more than 5 days per year in the state and (1) engage in the marketing of prescription drugs or (2) meet with HCPs to answer questions or provide product information.
NJ	**Limitation:** New Jersey prohibits HCPs licensed in New Jersey from accepting meals accompanying a promotional interaction valued at greater than $17 per person for breakfast and lunch, and $35 per person for dinner.	
OR	**Aggregate Spend Disclosure Report:** Manufacturers are required to keep a log of the nature, frequency, and duration of interactions with HCPs within the state, as well as the value and purpose of any items of value provided to HCPs.	**Pharmaceutical Detailer Licensure and Registration:** Pharmaceutical representatives who market SKLSI products in Oregon for more than 15 days per year must be licensed.
VT	**Aggregate Spend Disclosure Report:** Manufacturers are required to report the value, nature, purpose, and recipient information for payments made as part of a contractual arrangement.	**Prohibition:** Vermont prohibits providing gifts, educational items, and meals to all HCPs licensed in Vermont, regardless of the event location or where the HCP is currently practicing.

Link to **Glossary** >>

Transparency Reporting Laws *(continued)*

LOCAL LAWS		
Chicago	**Pharmaceutical Detailer Licensure and Registration:** Pharmaceutical representatives who market or promote pharmaceuticals within city limits for more than 15 calendar days per year must be licensed.	**Aggregate Spend Disclosure Report:** Manufacturers are required to keep a log of the nature and duration of interactions with HCPs within city limits, as well as the value and purpose of any items of value provided to HCPs. This applies to any HCP who is licensed to provide healthcare services or to prescribe *Schedule II* pharmaceutical or biologic products.
Miami (Dade County)	**Pharmaceutical Detailer Licensure and Registration:** Pharmaceutical representatives who interact with employees of Miami (Dade County) or Jackson Health System for the purpose of selling, marketing, or influencing a decision to purchase a product must register with the county as a "lobbyist."	**Disclosure Report:** All individuals registered as a "lobbyist" must submit a signed statement under oath stating all lobbying expenditures by category over $25 for the previous calendar year, regardless of whether the lobbyist incurred expenditures.

Link to **Glossary** >>

DOCUMENTATION REQUIREMENTS

Capturing All Relevant Attendee Information

Please note that SKLSI has established transparency reporting systems and processes to ensure accurate and timely reporting. It is important that you capture and report all relevant data in an accurate, complete, and timely manner, as SKLSI uses this data in a variety of ways, including the calculation of per-person meal costs. For example:

- For meals provided in an HCP's office, SKLSI calculates the per-person cost based upon the actual number of individuals who participated in the meal.
- For meals provided as part of a speaker program, SKLSI calculates the per-person cost based upon the number of individuals expected to participate in the meal. Where applicable, "no shows" should be captured to accurately adjust the per-person cost.

Expense Documentation

All meals provided to HCPs during in-office interactions or at speaker programs must be supported by the appropriate documentation, which includes:

- A completed SKLSI sign-in sheet
- An itemized receipt

You are responsible for ensuring:

- Meal sign-in sheets are accurately and completely filled out
- All transfers of value are documented accurately in the appropriate SKLSI system (e.g., Concur for in-office meals)

Remember, it is your responsibility to use the applicable SKLSI-approved paper or electronic sign-in sheet for all in-office educational programs and speaker programs, to enter your expenses on time, and to promptly assist with remediation activities as requested.

Link to **Glossary** >>

Concur Data Entry Process Overview: HCP Meal Expenses

Summary of Data Entry Requirements		
Reporting Jurisdiction	**Reportable HCPs**	**Concur Entry Process**
Federal Sunshine Act	MDs, DOs, Fellows, PAs, APRNs, NPs, CNSs, CRNAs, CNM	Add via IQVIA OneKey **Advanced Search** function ***Note:*** *Reportable attendees not found in the search must be entered individually as "Healthcare Staff (not prescribers)"*
District of Columbia (DC)	RNs, Pharmacists (RPH, PharmD), Licensed Clinical Social Workers	Add individually as "Healthcare Staff (not prescribers)" via free text using **New Attendee** function (if not found via IQVIA OneKey Advanced Search)
Massachusetts (MA)	RNs, Pharmacists (RPH, PharmD), Licensed Clinical Social Workers	Add individually as "Healthcare Staff (not prescribers)" via free text using **New Attendee** function (if not found via IQVIA OneKey Advanced Search)
Nevada (NV)	Individuals licensed or certified under the Nevada insurance code, Pharmacy Employees	Add individually as "Healthcare Staff (not prescribers)" via free text using **New Attendee** function (if not found via IQVIA OneKey Advanced Search)
Oregon (OR)	RNs, LPNs, Pharmacists (RPH, PharmD), Psychiatrists	Add individually as "Healthcare Staff (not prescribers)" via free text using **New Attendee** function (if not found via IQVIA OneKey Advanced Search)

Note: *Non-Reportable attendees may be grouped together as "Office Staff under "Healthcare Staff (not prescribers)" along with the Attendee Count*

Link to **Glossary** >>

DATA ENTRY REQUIREMENTS: SUNSHINE ACT REPORTING

Note: Additional steps for DC, MA, NV, OR can be found on the next page for specific process requirements for these states.

1. Select **Add Expense**
   - Selecting this option will open a blank expense.
2. Choose **Expense Type**
   - In Office HCP Meals, or
   - External HCP Breakfast / Lunch / Dinner (for those permitted to participate in external meals with HCPs)
3. Enter **Expense Details (if not prepopulated)**
   - Transaction Date
   - Business Purpose
   - Vendor Name
   - City of Purchase
   - Payment Type
   - Amount
   - Office Name, City & State
4. Select **Advanced Search**
   - Selecting this option will open the **Search Attendees** window
5. Choose **Attendee Type**
   - OneKey US Healthcare Organizations
   - OneKey US Healthcare Professionals
6. Enter **Search Criteria**
   - Best results will be generated using multiple data points when searching, e.g.:
     - — HCP First and Last Name
     - — NPI Number
     - — State License Number
     - — State

   Review search results and select the correct HCP Attendee
7. Click **Add to List** to add HCP to the expense item

   Note *— If the HCP is not available via the OneKey US Healthcare Professionals / Organizations Advanced Search function:*
   - Select **New Attendee**
   - Choose Attendee Type "Healthcare Staff (not prescribers)".
   - Enter as much detailed information as available (name, title, specialty, license #, city, state, etc.).
   - Select Save to close window
   - Enter comment stating that one or more of the attendees could not be locating in the OneKey search
8. Count the total number of Non-Reportable HCP Staff and enter as Office Staff in the Attendee Name, along with the number of individuals in the Attendee Count
   - Examples include: RN*, Billing Coordinator, Social Worker, Office Staff

   **Acceptable in areas not included in the State Specific Requirements*
9. Review the **Cost Allocation** to confirm all attendees were accurately accounted for
10. Attach **Receipt** and **Sign-In Sheet** to expense report

Link to **Glossary** >>

STATE SPECIFIC REPORTING REQUIREMENTS

District of Columbia (DC) Requirements

In addition to the reportable HCPs under the Federal Sunshine Act Reporting Requirements, the following must be individually reported as part of the DC requirements:

- RNs
- Pharmacists (RPH, PharmD)
- Licensed Clinical Social Workers

Massachusetts (MA) Requirements

In addition to the reportable HCPs under the Federal Sunshine Act Reporting Requirements, the following must be individually reported if the meal is >$50 per participant as part of the Massachusetts requirements:

- RNs
- Pharmacists (RPH, PharmD)
- Licensed Clinical Social Works

Nevada (NV) Requirements

In addition to the reportable HCPs under the Federal Sunshine Act Reporting Requirements, the following must be individually reported as part of the Nevada requirements:

- Individuals licensed or certified under the Nevada insurance code
- Pharmacy Employees

Oregon (OR) Requirements

In addition to the reportable HCPs under the Federal Sunshine Act Reporting Requirements, the following must be individually as part of the Oregon requirements:

- RNs
- LPNs
- Pharmacists (RPH, PharmD)
- Pyschiatrists

For each of the additional State Specific Reporting Requirements, perform the following steps to capture these additional individuals accurately and completely:

1. Follow steps 1-3 described in the *Federal Sunshine Act Reporting Requirements Process*
2. Then, select **New Attendee**
3. Choose **Attendee Type**
   - Healthcare Staff (not prescribers)
4. Enter all HCP information—Name, Company, Credentials, State
5. Click **Save** to add Attendee to the expense
6. Review the **Cost Allocation** to confirm all attendees were accurately accounted for

Note: *HCPs added through the New Attendee function can be accessed later using the Advanced Search function.*

Link to **Glossary** >>

Interactions with Other SKLSI Functions

- SKLSI maintains appropriate separation between Commercial and Medical functions, while providing the highest quality of information to Healthcare Professionals (HCPs) and other stakeholders
- In general, field-based Commercial employees and Medical employees cannot be present together with HCPs
- However, field-based Commercial and Medical employees may participate in HCP introductory meetings as further described in this policy

Interactions with Medical Science Liaisons (MSLs)

Interactions with MSLs should focus on high-level, general market intelligence. These interactions must never focus on discussing specific sales or promotional strategies for targeting HCPs. Appropriate coordination is permitted consistent with the guidance provided below. A Medical Information Request Form (MIRF) is not required for Commercial Associates requesting an MSL visit. However, a MIRF is required for off-label questions. Off-label questions may not be forwarded directly from Commercial Associates to MSLs. All requests must first be documented in a MIRF and submitted to Medical Information.

External Interactions with HCPs

Field Sales Associates may:

- Participate in brief introductory meetings between MSLs and HCPs provided:
  - The field-based Commercial employee does not engage in promotional discussions while the MSL is present
  - The MSL does not engage in scientific exchange or respond to off-label questions while the field-based Commercial employee is present
- NOT be accompanied by MSLs on promotional calls with HCPs
- NOT organize, provide, or participate in meals at Medical activities

Pharmacy and Therapeutics (P&T) Committee Interactions

For meetings with a P&T Committee intended to discuss the inclusion of SKLSI products on Formulary, SKLSI Sales Associates are expected to adhere to the following guidelines:

- Sales should reach out to their local MSL and HEOR colleagues to hold a pre-meeting to define the audience, approved deck, and roles for the meeting
- Sales can attend the P&T meeting with MSL and HEOR
- If scientific questions come up, Sales cannot participate in the discussion, but may remain in the room

Q: If I arrange an introductory visit between an MSL and an HCP, do I need to leave the room after the interaction?

A: Yes. You should leave the room for the scientific discussion. However, it is not necessary to leave the medical practice. For example, you may use this time to call on other HCPs separately from the MSL.

Q: If I am providing education to HCPs as part of a table-top exhibit at a third-party educational meeting, is it okay to interact with an MSL who is also attending the meeting?

A: While it is fine to greet and chat with your MSL colleagues at such events, interacting with an MSL at the exhibit table or during any other HCP-facing discussions would not be appropriate under our policies.

Q: As a KAM, I share some targets with my NAM colleagues. Is it appropriate to conduct a joint lunch?

A: Yes, you may conduct a joint lunch with your NAM colleagues. Remember that the guidelines for in-office meals apply; refer to the Meals and Educational Items chapter for additional information.

Link to **Glossary** >>

Grand Rounds

If requested by an HCP or HCO, SKLSI Sales Associates may:

- Coordinate an MSL to attend Grand Rounds and present an approved SKLSI deck
- Attend the meeting, but not participate in the presentation or discussion

Internal Interactions

Field-based Commercial employees may:

- Notify MSLs about HCPs who have expressed interest in conducting clinical trials or research
- Have alignment and coordinating interactions (e.g., by phone or during a business meal) with MSLs to discuss recently visited HCPs and to provide high-level HCP background information
- Receive company-approved training from MSLs on disease state or company products
- Discuss PMRC-approved clinical trial materials with MSLs
- Provide input on potential unmet medical education needs
- Use discretion when discussing off-label topics with MSLs internally and for information only (off-label topics cannot be used promotionally)
- NOT share specific sales goals, customer sales data, or sales and marketing tactics with MSLs
- NOT invite MSLs to attend promotional speaker programs

Link to **Glossary** >>

Conflicts of Interest

- SKLSI respects the rights of all Associates to engage in outside activities and manage investments in a way that does not interfere with their obligations to SKLSI
- SKLSI Associates must disclose potential Conflicts of Interest (COI) to their manager
- SKLSI managers will work with Human Resources to review potential COI

Overview

A COI occurs when an SKLSI Associate's private interest interferes, or appears to interfere, with SKLSI's business interest. Private interests may include (but are not limited to):

- Conducting business on behalf of SKLSI with friends, household members, or relatives
- Hiring, reporting to, or managing a close personal friend or relative
- Having a second job or role outside of SKLSI as a paid employee or consultant
- Holding an unpaid volunteer role
- Serving on a board or panel with a healthcare or patient organization (or other type of organization) or advising on healthcare issues
- Holding a significant financial investment (e.g., >5% of the entity) in a vendor, customer, or competitor of SKLSI
- Accepting gifts or entertainment of more than nominal value from a vendor, supplier, or consultant (particularly if linked to providing business, e.g., a restaurant offers gift cards in exchange for having a meal there)

SKLSI Associates are expected to:

- Perform their assigned professional duties in the best interests of SKLSI
- Avoid situations that could affect their ability to make unbiased professional decisions
- Avoid actual or perceived COIs where possible
- Disclose any potential conflicts for evaluation by SKLSI

Disclosing Conflicts of Interest

SKLSI Associates who have identified a potential COI should discuss the situation with their manager. Managers will determine if it is necessary to report the potential COI to the Human Resources Department for additional review. Managers and Human Resources will identify any steps that must be taken to mitigate the potential COI.

Remember: *Even if you are unsure if a situation presents a COI, you should dislose it to your manager. In cases where the potential conflict involves your manager, you should report the issue directly to the Human Resources Department.*

Q: An advocacy group invited me to be a member of their board. Am I permitted to accept the invitation?

A: Perhaps. Before accepting the invitation, you should follow the established disclosure process by notifying your manager, who will gather key information and escalate the invitation to Human Resources for additional review.

Q: I drive for Uber on the weekends. I use my personal vehicle (not a company-provided vehicle), and I do not drive during regular working hours. Is this ok?

A: Most likely. SKLSI Associates are permitted to have employment outside of SKLSI as long as that job does not interfere with your primary role with SKLSI, or require the use of company resources. A company-provided vehicle may not be used for driving Uber.

Q: My spouse owns a catering business and has offered to provide a discount on pricing if I use their services for in-office meals with HCPs. Is this permitted?

A: Probably not. Awarding business to a vendor on the basis of a personal relationship is considered a conflict of interest, and should be avoided.

Glossary: *Click term to return.*

Adverse Event	Any unfavorable, or unintended sign, symptom or disease, or change of an existing condition, which occurs during or after treatment with a drug or biologic product in humans, whether or not considered drug-related.
Caregiver	A person who provides care and support for a patient. Caregivers are often family members who may have specific insights into the challenges that patients may face in dealing with the applicable health condition.
Charitable Donation	Funding provided to a non-profit, tax exempt 501(c) (3) organization to support Patient education, advocacy, outreach, or the general well-being of the community in alignment with SKLSI's mission and values, for which SKLSI receives nothing in return.
Clinical Trial	Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.
Conflict of Interest (COI)	An actual or perceived conflict between an SKLSI Associate's private interests and their responsibilities to the Company.
Covered Recipient	Physicians (MD, DO, DDS, DPM, OD, DCP; excluding medical residents and mid-level prescribers (such as nurses, pharmacists, and physician assistants)) who are not employees of SKLSI; or teaching hospitals as identified by CMS.
Distribution-Only Reprint	A non-promotional, peer-reviewed scientific journal article containing scientific information or clinical data related to SKLSI products where the content may reference indications or uses that are not FDA-approved.
Educational Item	An item designed to advance disease or treatment education of an HCP or patient.
Exhibit	A booth, panel, table-top poster, or any other display at a program or event sponsored by a third-party organization.
Fair Balance	According to the FDA, the standard by which the content and presentation of a drug's most important risks are made reasonably similar to the content and presentation of its benefits..
Fair Market Value (FMV)	The price agreed upon between a reasonable buyer and a reasonable seller (or service provider) and which is comparable to prices ordinarily paid for the service in that particular location by parties in arm's-length transactions (i.e., transactions between independent and unrelated parties).
Federal Sunshine Act	A federal law requiring the annual public reporting of payments, reimbursements, and other transfers of value provided to covered recipients.

Form	The method of payment used to pay a covered recipient or to make a transfer of value (e.g., cash or cash equivalent; in-kind items and services; stock, stock option, other ownership interest, dividend, profit, or other return on investment).
Formulary Committee	A group of HCPs and/or business personnel responsible for determining a list of drugs and devices covered by a hospital or insurance company based upon the medical and cost effectiveness.
Gift	Benefits of any kind given to someone as a sign of appreciation or friendship without expectation of receiving anything in return. Examples of gifts include cash and cash equivalents, and "celebratory" or "courtesy" gifts which are small gifts, such as flowers given at culturally recognized occasions (e.g., weddings, bereavement) or special times of the year (e.g., Christmas, New Year). Entertainment is also considered a gift, including tickets to sports events, plays, and other entertainment/recreational events.
Grant	Medical education programs, including accredited, non-accredited, and patient education programs supported by SKLSI.
Healthcare Economic Information (HEI)	Information such as treatment guidelines, health outcomes data, pharmacoeconomic, or population-based outcomes for the purposes of patient access, as well as other analyses that identify, measure, or compare the economic costs of health outcomes with the use of one drug versus another, with the use of one drug versus a different intervention, or versus no intervention at all.
Healthcare Organization (HCO)	Any organization or institution that provides healthcare services to patients. Examples include: Academic medical centers, hospitals, and clinics.
Healthcare Professional (HCP)	Any individual or entity that can, in his or her professional capacity, influence the use, purchase, prescription, or recommendation of SKLSI products, or affect the formulary or other preferential or qualifying status of SKLSI products, including but not limited to, doctors, nurses, pharmacists, medical students, teaching institutions, formulary committee members, and clinical trial investigators.
Investigator Initiated Studies (IIS)	Research conducted by an outside investigator supported by SKLSI through a grant or contract where the investigator serves as the study's sponsor and is responsible for compliance with all regulatory submissions and requirements, as defined by the FDA.
Managed Care Organization (MCO)	A group of physicians or doctors which patients can visit as part of a prepaid health care system, in which patients are entitled to services rather than paying a dollar amount guaranteed by an insurance policy.
Meal	A portion of food or drink, including breakfast, lunch, snacks, or dinner.
National Provider Identifier (NPI)	A unique 10-position numeric identification number for HCPs and HCOs used for federal reimbursement.

Nature	Categories used to describe why a payment or other transfer of value was made to an HCP or teaching hospital (e.g., Consulting Fees, Food and Beverage, Travel and Lodging).
Off-Label	Information about a SKLSI product inconsistent with the use(s) described in the FDA-approved product labeling.
Package Insert (PI)	A pamphlet that accompanies drugs containing details and directions HCPs need to properly prescribe the drug. It is also the basis for how the drug company can advertise its drug.
Patient	Any person with a potential or diagnosed health condition who may purchase, consume, or receive medical treatment for the condition.
Patient Conferences	Events attended by patients and caregivers at which they can learn information about disease states and potential treatment options.
Patient Organization	Also referred to as a patient advocacy group, a Patient Organization is a non-profit organization mainly composed of patients and/or caregivers, that represents the needs and interests of, and provide support to patients and their caregivers, relatives, and friends.
PhRMA Code	An industry code of conduct, which SKLSI abides by, that establishes proper and improper interactions with HCPs related to the marketing of drug products.
Prescriber Data	Any data pertaining to statistics and practices of a physician who prescribes SKLSI or competitor products to patients.
Product Complaint	Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a drug after it is released for distribution (e.g., broken tables, missing label).
Promotional Reprint	Reprint of medical journal articles and scientific of medical reference publications (generally referred to as medical and scientific information) that discusses information which may not be consistent with the product label.
Promotional Materials Review Committee (PMRC)	The SKLSI committee responsible for reviewing all promotional, advertising, and educational materials pertaining to products marketed or investigated by SKLSI.

Protected Health Information (PHI)	Individually identifiable health information protected under HIPAA.
Samples	A unit of drug not intended for sale, but rather intended to promote the sale of the drug by providing patients access without charge.
Speaker Program	Live or virtual programs designed to provide scientific and educational information to a group of invited HCPs regarding the use of SKLSI products, disease areas of interest to SKLSI, or other relevant healthcare topics.
Specialty	An HCP's area of medical expertise. HCPs with whom it is inappropriate to promote SKLSI products because the area of medical expertise is outside the approved product labeling are considered "Excluded Specialties."
Sponsorship	Funding provided to scientific societies, HCOs, Patient Organizations, or other entities in exchange for corporate recognition (e.g., advertising, banners, or signage) or for the payment of tangible items (e.g., booth space or registration at a medical conference).
Teaching Hospital	Hospitals that received payment for Medicare direct graduate medical education (GME), in-patient prospective payment system (IPPS), indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year.
Voucher	A certificate SKLSI provides to HCPs for Patients that are redeemed at a pharmacy for a free trial or reduced out-of-pocket cost for the prescription of an SKLSI product.

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US Commercial Field Compliance Manual:
Compliance Guidelines for Field Sales Interactions

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