

Compliance and Privacy Quick Reference for Marketing Pieces

This quick reference is not intended to be exhaustive. Please refer to the Guide to Compliance and Privacy Topics in Marketing Pieces for more information.

Compliance Quick Reference

<p>Does your marketing piece relate to a patient screening event or a physician CME?</p>	<p>If yes, please seek a Compliance review and share your operations contact with Compliance.</p> <p>If no, please see below.</p>
<p>Does your marketing piece involve any of the following?</p> <ul style="list-style-type: none"> • Giveaways to patients exceeding \$15 in value? • Giveaways to physicians? • Giveaways to referral sources or potential referral sources? • Raffles, bingo, or gambling? • Vendor involvement? • Entities other than UC Health, UC Physicians, UCMC, West Chester, Drake, the Women’s Center, or an institute such as UCCI or UCGNI? • A hospital advertising specific doctors? 	<p>If yes, please seek a Compliance review and share your operations contact with Compliance.</p> <p>If no, unless you have any specific questions for Compliance, please proceed. Ensure you have permission and proper context for all logos, and all claims are accurate.</p>

Privacy Quick Reference

<p>Does your marketing piece involve any of the following?</p> <ul style="list-style-type: none"> • A reference to a specific diagnosis or a class of individuals, and the material will not be in a sealed envelope? • The sharing of any PHI with an external consultant, contractor, printing company/shop, or firm for a marketing or story purpose, and you are unsure whether a contract and business associate agreement have been signed? 	<p>If yes, please seek a Privacy review.</p> <p>If no, unless you have any specific questions for Privacy, please proceed.</p>
<p>Does your marketing piece involve an incomplete or expired authorization?</p>	<p>If yes, please obtain a complete and appropriate authorization.</p> <p>If no, ensure there is a valid authorization, if one is needed. Unless you have any specific questions for Privacy, please proceed.</p>

Guide to Compliance and Privacy Topics in Marketing Pieces

Below please find explanations of common issues in Compliance and Privacy's review of marketing pieces. In many cases, questions will relate to the operations of an event being promoted, rather than the marketing piece itself. Compliance and Privacy appreciate Marketing's partnership and cooperation in avoiding and mitigating compliance and privacy risks.

1. Key Sources of Law:

- a. **Anti-Kickback Statute (AKS)** prohibits anyone from knowingly and willfully offering, paying, soliciting or receiving anything of value in order to induce or reward the referral or purchase of items or services.
- b. **Civil Monetary Penalty Law (CMPL)** prohibits the offer or transfer of anything of value to a patient that is likely to influence the patient's selection of a particular provider of any healthcare item or service.
- c. **Stark Law**, also known as the physician self-referral law, prohibits a physician from referring patients for certain "designated health services" to an entity with which the physician or the physician's immediate family member has a financial relationship (ownership, investment, or compensation).
- d. **Health Insurance Portability and Accountability Act (HIPAA)** dictates how healthcare entities and individuals may use and disclose patients' protected health information (PHI), as well as how they must safeguard patients' PHI.
- e. **Health Information Technology for Economic and Clinical Health Act (HITECH)** instituted the HIPAA Breach Notification Rule which requires healthcare entities to notify individuals within 60 days of discovery that the individual's PHI was inappropriately used or disclosed. HITECH tightened the requirements for healthcare entities to work with business associates (contractors who perform an operational task on a healthcare entity's behalf who will come into contact with PHI). HITECH also made changes to how healthcare entities may use and disclose protected PHI for marketing and fundraising purposes.

2. Compliance - Free or Discounted Items or Services:

- a. Patients - Offering or Providing Free or Discounted Items or Services:
 - i. There could be AKS or CMPL implications, as both laws control when patients or potential patients can be offered or gifted free or discounted items/ services.
 - ii. An AKS or CMPL analysis is required for a marketing piece that describes an event with something free or discounted, or a marketing piece that itself includes an offer of something free or discounted. The "something" can be tangible, or intangible. Common examples are free food and promotional items.
 - iii. It is acceptable to provide free or discounted items/ services in certain circumstances.

- I. CMPL permits gifts of nominal value: less than \$15 per item and \$75 in the aggregate annually per beneficiary (these amounts are updated periodically; contact Compliance for questions). For example, it is acceptable for a patient mailer to offer a free first aid kit valued at \$4, or for a mailer to refer to a free continental breakfast (as long as the breakfast is valued at under \$15 per person). Cash or cash equivalents are never permissible, nor are any gifts intended to induce referrals.
 - II. The provision of free patient education is allowed under the law, and the education itself does not need to follow the \$15/\$75 rule, but if there are any further giveaways at the event, each giveaway needs to be compliant.
 - III. Free patient screenings can be offered under certain circumstances.
- iv. To learn more, please review the following policies: Free or Discounted Items or Services to Medicare or Medicaid Beneficiaries; Gifts To and From UC Health and UC Health Representatives; and Compliance with the Anti-Kickback Statute (AKS) and Stark Law. All policies are available on the UC Health intranet.
 - v. Please contact Compliance if the marketing piece involves something over the \$15/\$75 rule, a patient screening, or if Compliance policies do not resolve the issue. AKS and CMPL have exceptions, and Compliance can review matters on a case-by-case basis.
- b. Physicians - Offering or Providing Free or Discounted Items or Services:
- i. Stark or AKS may be triggered by a marketing piece that describes an event with something for free or for less than fair market value, or a marketing piece that itself includes an offer of something for free or for less than fair market value. The “something” can be tangible, or intangible. Common examples include free food, free marketing, or free/ discounted CME credit.
 - ii. Free marketing on behalf of a physician is considered “compensation” for Stark purposes, so marketing for physician(s) by a hospital (UCMC, West Chester, Drake) or by UCPC for non-UCPC physicians can present Stark concerns. Please seek Compliance guidance.
 - iii. There are several requirements for offering physicians something free or for less than fair market value.
 - I. Physicians can receive non-monetary compensation, up to \$423 annually (as of 2020), provided it is not cash or cash equivalent, does not take into consideration the volume or value of referrals by the physician, is not solicited by the physician, and does not violate the AKS by inducing/ rewarding referrals. Non-monetary compensation must be tracked to ensure that the annual limit is not exceeded per physician. If a physician is receiving something at a discount or for less than fair

market value, the value of the discount must be tracked. Contact Maryann Toney to add the value to the tracking spreadsheets.

- iv. To learn more, please review the following policies: Free or Discounted Items or Services to Physicians (formerly Non-Monetary Compensation and Medical Staff Incidental Benefits); Gifts To and From UC Health and UC Health Representatives; and Compliance with the Anti-Kickback Statute (AKS) and Stark Law.
 - v. Please contact Compliance if free or discounted items or services are being offered or gifted to physicians.
- c. Referral Sources or Potential Referral Sources - Offering or Providing Free or Discounted Items or Services:
- i. There could be AKS implications, as the law prohibits offering anything of value in order to induce or reward referrals.
 - ii. It is never acceptable to offer or provide free or discounted items or services to referral sources or potential referral sources if the intention is to induce or reward referrals or business. It is also unacceptable to do so if the gift could give an impression of inducing or rewarding referrals or business, even if that is not the intention. For this reason, gifts such as free event tickets to EMS providers or vendors carry significant compliance risks. Please contact Compliance if you have any questions.
 - iii. To learn more, please review the following policies: Gifts To and From UC Health and UC Health Representatives; and Compliance with the Anti-Kickback Statute (AKS) and Stark Law.

3. Compliance - References to Non-UC Health Entities:

- a. UC Health is the sole member of UCMC, West Chester, Drake, and UCPC. The Lindner Center of Hope is a joint venture with UC Health, and so services should only be provided to Lindner when there is a relevant contract in place.
- b. Marketing Involving UC Health, together with UC, the UC Health Foundation, and/or the UC Foundation:
 - i. Legally, UC Health and UC are separate entities with an affiliation agreement defining their relationship and providing for each entity's rights and obligations in connection with UC Health's academic medical center status. The UC Health Foundation and UC Foundation are also separate entities, and how funds flow to and from each foundation can have financial and compliance implications.
 - ii. It is important to avoid confusion about which entity is involved in a particular event or piece of marketing. If Marketing is promoting an event that involves multiple entities, or entities other than UC Health, UC Physicians, UCMC, West Chester, Drake, the Women's Center, or an institute such as UCCI or UCGNI,

seek Compliance guidance. For example, consider whose branding is on the marketing piece, and who the RSVP contact is, and whether these are consistent.

iii. It is important to make sure that patient PHI is not being provided to UC staff (or any other outside entity) in the course of planning or inviting patients to events.

c. Use of Non-UC Health Logos.

i. There can be legal consequences for unauthorized use of other entities' logos. It is only acceptable to use a non-UC Health logo on a marketing piece when the owner of the logo has granted permission for its use.

ii. Consulting with Compliance is not necessary if Marketing has permission to use the logo(s) in the marketing piece and the logo is used in the proper context. For example, a US News & World Report designation for UCMC should not be used for West Chester or UCPC marketing pieces.

4. Compliance - References to Volume or Value of Physician Referrals:

a. It is never acceptable to refer to volume or value of physician referrals, because of AKS and Stark. Please contact Compliance if a marketing piece refers or relates to the volume or value of physician referrals.

5. Compliance - References to Continuing Education Credit:

a. There are certain accreditation requirements for events offering continuing education credits. Marketing or operations should confirm with the UC CME team that the marketing piece is approved, uses the appropriate statement(s), and the event qualifies for credit.

6. Compliance - Raffles and Related Activities:

a. Ohio law strictly regulates activities including raffles, bingo, instant bingo, and games of chance or skill.

b. Door prizes (where every attendee receives a drawing entry and has an equal chance of success) are acceptable, provided they are not conditioned on or related to a patient's receipt of health services. The prizes, including gift baskets must be consistent with Compliance's policies, and the value of a free item provided to patients must be less than \$15, calculated by dividing the prize value by the number of entrants to the drawing. Any description of a door prize must indicate that entry is not tied to receipt of health care items or services.

c. Please seek a Compliance review if the event or marketing piece includes a raffle or similar event.

7. Compliance - Accuracy of Claims

- a. Are the statements accurate and precise? For example, a marketing piece should not say that UC Health is the only academically based cancer center in Cincinnati, when it is the only adult academically based cancer center. Please contact Compliance with questions.

8. Privacy – Use and Disclosure of Protected Health Information for Marketing

- a. The Privacy Rule defines marketing as “a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.” (45 CFR § 164.501).

9. Privacy – Do I Need an Authorization?

- a. Authorization is needed if the marketed information contains any ***one or more*** of the following protected health information (PHI):
 - i. Name,
 - ii. Geographic Location smaller than a state,
 - iii. Any date associated with a patient; If a patient is 90 or older, then their age by itself is PHI; If a patient is 89 or younger, their age is not PHI,
 - iv. Phone and Fax Numbers,
 - v. Email Addresses,
 - vi. Social Security Numbers,
 - vii. Medical Record Numbers,
 - viii. Insurance Beneficiary Numbers,
 - ix. Account Numbers,
 - x. Certificate or License Numbers,
 - xi. VINs and License Plates,
 - xii. Device Identifiers and Serial Numbers,
 - xiii. Web Addresses,
 - xiv. IP addresses,
 - xv. Biometric Identifiers (Fingerprints, voice prints, etc.),
 - xvi. Full-face photographic images and other comparable images,
 - xvii. Any other unique number, characteristic, or code (**such as a rare diagnosis, unique tattoo, unique story/background**), or

- xviii. UC Health receives any sort of remuneration (direct or indirect payment from or on behalf of a third party whose product or service is being marketed) from use of the PHI, then
 - xix. You should have the patient completely fill out the approved *Authorization for Marketing & Media Interview, Photograph, and/or Videotape* form. An incomplete form is an invalid authorization. Any disclosure made based on an invalid authorization is a violation of HIPAA.
- b. To learn more, please review the following policy: Authorization for Release of Patient Protected Health Information (PHI). All policies are available on the UC Health intranet.

10. Privacy – Consent or Authorization?

- a. The Privacy Regulations make a distinction between “consent” and “authorization.” Consent is never needed to use or disclose protected health information, and authorization is only needed sometimes. “Consent” and “authorization” are not interchangeable.
- b. Consents typically provide permission in more general terms, and do not always need to be written. Authorizations are very specific in their descriptions of what information will be used and how it will be used. Authorizations must be written, they must include 12 elements (verify the 12 with the Privacy Office), and if any one element is missing or incomplete, the authorization is not valid.
- c. Consents may be needed for risk management, regulatory accreditation, or department operations purposes. Please verify with the other departments if they will need you to obtain consent.
- d. A valid authorization must be obtained from the patient any time UC Health will use or disclose protected health information without a treatment, payment, or operations reason.
- e. There is no “one and done” authorization. The authorization will only be valid in the timeline specified, for the purposes specified, and it must be obtained before any disclosure, picture, or recording occurs. An authorization to use/disclose information specifically for a service/specialty may not be used for other services/specialties, unless the authorization allows it or a new authorization has been obtained.
- f. As long as the use/disclosure of PHI is within the scope of the authorization and within its expiration date, you may use/disclose the PHI as many times as you would like for that purpose.
- g. A patient or his or her legal representative may revoke his or her authorization for release of PHI, except to the extent that action has already been taken on the authorization. To learn more, please review the following policy: Authorization for Release of Patient Protected Health Information (PHI).

11. Privacy – How Do I Know If the Mailer I Want to Send out Needs an Authorization, or If It Needs to Be in a Sealed Envelope?

- a. If the communication promotes health in a general manner, you do not need an authorization or a sealed envelope.
 - i. For example, if UC Health sends a mailer about the benefits of exercise and a healthy diet to all of its patients, there are no privacy concerns, and this is not considered “marketing” under the Privacy Regulations.
- b. If the communication is going to a specific class of people (e.g., patients with a specific condition) to tell the people about treatment, case management, care coordination, or alternative therapies, an authorization is not needed, but it would be appropriate to send that in a sealed envelope.
 - i. For example, if UC Health sends information about an alternative treatment for a specific type of cancer to patients being treated for that type of cancer, an authorization would not be needed from each patient to receive that information, but it should be sent in a sealed envelope.
- c. If the communication does not contain PHI, and it was not obtained from a patient list, rather it is going to an entire community regardless of their patient status with UC Health, you do not need an authorization or a sealed envelope.
 - i. For example, if UC Health sends a mailer about a new clinic opening in a community and all members of that geographic area receive a notice because of where they live, there are no privacy concerns. Even if it goes to some active patients, if PHI was not used to generate the addresses/list of recipients, then nothing additional is needed.
- d. If the communication is a newsletter or other publication that contains a specific patient’s “Success Story,” the patient must authorize use of his/her “story” before it can go out on a mailing list.
 - i. For example, all of UC Health’s patient ambassadors should have completed the appropriate authorization form prior to the sharing of their stories. As long as UC Health detailed how the information will be shared, and the information is used within the scope of the authorization, UC Health does not need any further permission.

12. Privacy – Business Associates

- a. Prior to sharing any PHI with an external consultant, contractor, printing company/shop, or firm for a marketing or story purpose, you should ensure that a contract and business associate agreement has been signed.
- b. PHI should never leave UC Health (including UCMC, West Chester, Drake, and UCPC) and be sent to an external company or person unless the appropriate agreements are in place. Sending information outside of the organization without an appropriate

agreement and business associate agreement maybe be a violation of the law and is a violation of UC Health policies.

13. Privacy – When Should I Send Something to the Chief Privacy Officer for Review?

- a. Any time a marketing material will be sent out and it makes reference to a specific diagnosis or a class of individuals, but the material will not be sent in a sealed envelope, it should be sent to the Chief Privacy Officer for review.