

Health Care Compliance and Sunshine Act

Glossary of Terms

CMS – Centers for Medicare and Medicaid

Covered product – also called covered device, is a device in which payment is available under CMS and requires pre-market approval or clearance by the FDA.

HCP – health care professional (includes physicians and dentists)

HCT/P – human cells, tissues, and cellular and tissue based products

Non-covered product – HCT/Ps that are not regulated as medical devices, drugs, or biologics

Frequently Asked Questions

Q1. Are gifts to HCPs of nominal value acceptable?

A1. No, gifts to HCPs are not permissible under the LNH Healthcare Compliance Procedure QS-90-001 Interactions with Health Care Professionals.

Q2. Is it acceptable for an employee of LifeNet Health to offer social entertainment, such as golf or event tickets, to a HCP or teaching institution?

A2. No, entertainment is prohibited under LNH procedure QS-90-001 Interactions with Health Care Professionals.

Q3. Are employees allowed to extend business courtesies to guests/spouses of HCPs in connection with sales and promotional meetings or other LNH events?

A3. No, business courtesies to guests/spouses of HCPs are not permissible under the LNH Healthcare Compliance Procedure QS-90-001 Interactions with Health Care Professionals.

Q4. Is it acceptable to give a surgeon who purchases LifeNet Health tissue an iPad for patients so they can view educational materials about allograft tissue and/or an upcoming surgical procedure?

A4. No, an iPad is considered a gift, which is not permissible under QS-90-001 Interactions with Health Care Professionals.

Q5. Are educational materials reportable transfers of value?

A5. Educational materials and items that directly benefit patients or are intended to be used by or with patients are not reportable transfers of value. Additionally,

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the value of LNH's services to educate patients regarding a covered drug, device, biological, or medical supply are not reportable transfers of value. For example, overhead expense, such as printing and time development of educational materials, which directly benefit patients or are intended for patient use are not reportable transfers of value. Educational materials that have no patient benefit or do not directly benefit the patient are reportable transfers of value.

Q6. Are items or materials used to educate physicians, which may indirectly benefit patients reportable?

A6. Yes, educational materials, such as medical textbooks or journal reprints, that are educational to physicians, but are not intended for patient use or directly beneficial to patients, are reportable and must be disclosed to LifeNet Health.

Q7. Should LNH report a payment that was made to a physician or to a clinic if a specific physician practicing at the clinic performs the services? Is this considered an indirect payment?

A7. This is considered an indirect payment. LNH is required to report indirect payments to physicians. A payment is considered indirect if the payment is made to a third party to provide the payment in whole or in part to a physician. An indirect payment was made to the physician since a certain physician at the clinic performed the services. The payment made to the clinic was ultimately transmitted in part to the physician through the clinic.

Q8. If LNH makes a payment or transfer of value to a group practice rather than a specified physician, how should LNH correctly report the payment or transfer of value? Should the payment be reported in the name of the physician or to all of the physicians included in the group practice?

A8. A payment or other transfer of value provided to a group practice (or multiple covered recipients generally) should be attributed to each individual physician covered recipient who requested the payment or performed the services. LNH should divide payments or other transfers of value in a manner that most fairly represents the situation.

Q9. Are payments provided to physicians for speaking at a continuing medical education event reportable?

A9. No, speaker compensation at continuing education events such as a Continuing Medical Education (CME) conference is not required to be reported by LNH if all of the following criteria are met:

- (1) the CME program meets the accreditation or certification requirements and standards of the Accreditation Council for Continuing Medical Education, the American Academy of Family Physicians, the American Dental Association's Continuing Education Recognition Program, the American Medical Association, or the American Osteopathic Association,
- (2) LNH does not select or suggest the covered recipient speaker nor does it provide the third party vendor with distinct, identifiable individuals to be considered as speakers for the accredited or certified continuing education programs; AND
- (3) LNH does not directly pay the covered recipient speaker.

Q10. Are payments for medical research writing and/or publication included in reporting research payments?

A10. A payment reported as research falls within a research payment category if it is subject to either: 1) a written agreement; 2) a contract; or 3) a research protocol. Payments for medical research writing and/or publication would be included in the research payment.

Q11. Will CMS notify physicians and teaching hospitals that LNH and other applicable manufactures reported data about them?

A11. Physicians, teaching hospitals, and physician owners or investors will receive a general notification when the reported information is ready for review. However, the physician, teaching hospital, and physician owners or physician investors will only receive this notification if they have previously registered with CMS.

Q12. What if LNH utilizes the Vet School or Engineering School of a university for an animal study or other type of pre-clinical research? Are these payments reportable?

A12. The research proposal and agreement shall be reviewed in accordance with the Contracts Administration SOP to ensure health care compliance and Sunshine Act issues are addressed. No commitment should be made and no agreement executed until approved by authorized LNH personnel.

Q13. What if LNH is conducting pre-clinical or clinical research to support a pre-market submission for marketing a new product? When are these payments reportable?

A13. The Sunshine Act allows manufactures like LNH to delay reporting payments related to pre-clinical and clinical research for new products that require FDA approval or clearance so that companies can protect new technology and

proprietary information from becoming public before the product is placed on the market. It is important you work with Finance to identify these payments and determine the appropriate time allotment for the delay allowed under the Sunshine Act.

Q14. Can I provide a gift to an employee of a university that is not affiliated with the medical school to thank them for their hard work on a collaborative project?

A14. No, providing gifts to consultants and/or employees of universities has the potential for violations of the Anti-kickback Statute and the potential for reporting based on a number of considerations. Therefore, gifts and entertainment are not permitted.

Q15. Is it ok for me to provide an HCP or hospital with an evaluation sample and complete the form at a later date?

A15. No, the form must be completed and approved prior to shipping or providing an evaluation sample.

Q16. Is it ok for me to provide research tissue to an HCP, research facility, or hospital without completing the forms because I already have it available and I know it's not reportable?

A16. This is not appropriate and the research tissue request forms must be completed and approved prior to providing any research tissue. The Finance Department will determine if the transfer of value is reportable.

Q17. What if a doctor's office won't see me without bringing in food for the entire staff?

A17. Under LNH's compliance procedure, it is permissible to provide a meal during a sales call or meeting with a Physician when the meal is secondary to the exchange of scientific, educational, or clinical information. However, only those that are a part of that meeting can be provided a meal. It would not be appropriate to provide a meal to the entire staff or department.

Q18. What are the brand names of LNH medical devices? This list is located on Document Control.

A18. MatrACELL[®] Decellularized Pulmonary Artery Patch Allograft
Optium[™] DBM Putty
I/C Graft Chamber[®]
Kinetigraft[®]
Triple Bundle[®]
Lateral Ankle
GraftLink[®]

Q19. How should a payment/expenditure be captured/reported if it is related to a medical device (covered product) and a HCT/P (non-covered product)?

A19. All payments/expenditures should be captured and disclosed to LNH. The entire value of the payment/expenditure is reportable and the names of the products are included in the report.

Q20. Payments made by distributors and marketing partners – are we required to report?

A20. LNH is not required to report indirect payments or transfers of value made through a 3rd party in situations where LNH is unaware of the identity of the covered recipient. The distributor/partner will be required to report that payment, not LNH since we are unaware of the identity of the covered recipient.

If LNH is making a payment to a 3rd party, reimbursing a 3rd for a payment or expenditure, and we know the identity of the covered recipient, we are required to report.

Q21. Who do I contact if I have more questions, need some guidance, or to report potential violations of the law and/or LNH policies and procedures?

A21. There are three options available:
Hotline: 2211
E-mail: compliance@lifenethealth.org
In person: Regulatory Affairs or Office of the CFO