# OVERVIEW OF THE LEUKEMIA & LYMPHOMA SOCIETY'S (LLS) COMPLIANCE PROGRAM

The U.S. Department of Health and Human Services, Office of the Inspector General (the "OIG") has identified seven (7) elements that are fundamental to any Compliance Program. LLS has a steadfast commitment to compliance and has implemented a Compliance Program based on the OIG's 7 elements, as described in more detail below. Questions about LLS's Compliance Program should be directed to Dale Nissenbaum, EVP, General Counsel at dale.nissenbaum@lls.org or by calling 914-821-8824.

The OIG's 7 Elements of an Effective Compliance Program are:

- 1. Written Policies and Procedures
- 2. Designated Committee Overseeing Compliance
- 3. Effective Compliance Training and Education
- 4. Established and Open Lines of Communication
- 5. Internal Monitoring and Auditing
- 6. Enforcement Protocols
- 7. Prompt Response and Corrective Action Protocols

#### The LLS Compliance Program:

#### 1. Written Policies & Procedures

- LLS has implemented written standards which are reflected in its' Code of Ethics and Professional Conduct (the "Code of Conduct"), Conflict of Interest Policy, Employee Handbook, and the Co-Pay Assistance Program Compliance Standard Operating Procedures ("Co-Pay Compliance SOPs").
- All LLS directors, officers, and employees are expected to abide by the Code of Conduct as well as all other LLS policies and procedures.
- All external partners and vendors responsible for administering LLS's Co-Pay Program are required to abide by the principles outlined in the Co-Pay Compliance SOPs.

## 2. Designated Compliance Committee -

- LLS's Co-Pay Program is overseen by LLS's Audit Committee of the Board of Directors. The Audit Committee can be contacted through LLS's EVP & General Counsel, Dale Nissenbaum at dale.nissenbaum@lls.org.
  - The Audit Committee's responsibilities include: overseeing LLS's Compliance Program, including periodic review and approval of compliance program documents; receipt of compliance program updates, including the results of the annual Co-Pay Program Audit; review of the proposed development of new Co-Pay funds or changes to existing Co-Pay funds; and receiving and investigating compliance-related complaints including through LLS's Ethics & Compliance Hotline.

# 3. Annual, effective education and training, including training on LLS's Office of Inspector General ("OIG") Advisory Opinion

- All LLS employees are required to accept/sign the Code of Conduct each year and complete compliance training during onboarding and annually thereafter.
- All LLS Co-Pay Program employees are required to complete compliance training during onboarding and on an annual basis thereafter.
- LLS vendors involved with LLS's Co-Pay Program receive a modified version of LLS's compliance training on an annual basis.
- LLS's Human Resources Department maintains records of employee training and policy sign-offs.
- Co-Pay Training may include the following topics:
  - Review of OIG guidance, including LLS's OIG Advisory Opinion
  - Review of potential fraud, waste, and abuse concerns
  - Laws and regulations applicable to LLS (e.g., Anti-Kickback Statute, privacy laws)
  - Elements of LLS's Compliance Program

### 4. Reporting channels, including anonymous reporting hotline

- All LLS employees have a duty to report any suspected violation of law, regulation, OIG guidance, LLS's Advisory Opinion, LLS's Anti-Discrimination and Anti-Harassment Policy, or any other LLS policy or procedure.
- Failure to report may lead to disciplinary actions up to and including termination of employment.
- Report Suspected or Actual Violations of the Law or LLS Policy or Procedure to:
  - Your supervisor or other managerial personnel in your chain of command:
  - The Human Resources Department;
  - The Legal Department;
  - Any member of the Audit Committee; or
  - Anonymously: available 24/7 through LLS's Ethics and Compliance Hotline at 1-800-736-0493
- To the extent possible, reports of suspected or potential violations will remain confidential.
- Managers who receive reports of suspected violations of the law, including OIG guidance or LLS's Advisory Opinion, must report the suspected violations immediately to the Legal Department or a member of the Audit Committee of the Board of Directors.
- LLS will not tolerate any form of retaliation for good-faith reporting of a perceived instance of fraud, waste, or abuse, or a suspected violation of law, regulation, OIG Guidance, LLS's Advisory Opinion, LLS's Anti-Discrimination and Anti-Harassment Policy, or any other LLS policy or procedure.

### 5. Annual Co-Pay Assistance Program audit and periodic, ongoing monitoring activities

- LLS engages an Independent Review Organization to conduct an annual Co-Pay Program audit to assess LLS's compliance with applicable laws, regulations, guidance, LLS's OIG Advisory Opinion, and LLS's Co-Pay Program policies and procedures.
- LLS conducts (or instructs a vendor to conduct on LLS's behalf) informal monitoring activities to ensure day-to-day compliance with Co-Pay Program operational requirements.
- Audit findings and issues identified through informal monitoring activities are reported to the Audit Committee every quarter.

#### 6. Publicized disciplinary guidelines

 LLS employees are subject to disciplinary action, up to and including termination of employment for violating applicable laws, regulations, guidance, LLS's OIG Advisory Opinion, or other LLS policies or procedures.

# 7. Mechanisms to respond to potential incidences of non-compliance and develop corrective action as necessary

- All employees are obligated to cooperate with LLS in investigating suspected compliance violations.
- When a compliance concern or violation is identified, a written corrective action plan
  will be developed to address the specific compliance issue and prevent similar issues
  from occurring in the future.
- Corrective action may include recommendations for disciplinary action.
- The results of investigations into suspected compliance violations, along with any recommended corrective actions will be reported to the Audit Committee every quarter.