

I. PROHIBITIONS ON KICKBACKS AND FALSE CLAIMS

A. Background

- 1. As a recipient of federal funds from the Medicare and Medicaid programs, PACE Organization is subject to the requirements of various federal and state laws, including laws prohibiting the payment of kickbacks or other remuneration in order to influence Federal Health Care Program business. Specifically, the AntiKickback Statute prohibits:
 - the knowing and willful solicitation or receipt of any remuneration (direct or indirect, overtly or covertly, in cash or in-kind, including kickbacks, bribes or rebates) in return for a referral for the furnishing of any item or service payable under a Federal Health Care Program; or
 - the knowing and willful solicitation or receipt of any remuneration (direct or indirect, overtly or covertly, in cash or in-kind, including kickbacks, bribes or rebates) in return for purchasing, leasing or ordering or recommending purchasing, leasing or ordering, any good, facility, service or item payable under a Federal Health Care Program.

For purpose of the PACE Organization's PDP, the Anti-Kickback Statute prohibits conduct such as:

- A pharmaceutical company's payment of a fee to a physician for every prescription the physician writes for that company's drugs
- A P&T Committee member accepting a free trip from a pharmaceutical company in exchange for including the company's new drugs on a plan formulary
- A prescription drug plan paying a nursing home to influence all residents to sign up for that prescription drug plan

A violation of the Anti-Kickback Statute and similar federal and state laws may result in significant criminal and civil penalties, including civil monetary penalties and possible exclusion from participation in Medicare and Medicaid.

2. The False Claims Act prohibits knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval. Additionally, it prohibits knowingly making or using (or causing to be made or used) a false record or statement to get a false or fraudulent claim paid or approved by the federal government or its agents, like a carrier, other claims processor or state Medicaid program. A "claim" could include PDE and other data submitted to CMS, the PACE Organization "bid" and all other reports submitted to CMS for the purpose of receiving federal reimbursement.

For purpose of the PACE Organization PDP, the False Claims Act prohibits conduct such as:

- Submitting fabricated PDE data to CMS;
- Prescribing a particular drug for which there is no medical necessity;
 Falsifying data in the RAPS or other systems in order to induce a higher reimbursement or capitation rate; and
- Submitting data to CMS showing actual costs incurred for purposes of the reinsurance or other subsidy, when in fact such costs were not incurred.

Submission of a false claim in violation of the False Claims Act and similar federal and state laws could result in significant criminal and civil penalties, including civil monetary penalties plus three times the amount of damages the government sustained because of the false claim, and possible exclusion from participation in Medicare and Medicaid.

3. There are numerous other federal and state laws that govern the PACE PDP's operations, including the HIPAA Privacy and Security Rules and other state and federal anti-fraud laws. The listing of the False Claims Act and the AntiKickback Statute is not intended to suggest that these are the only laws governing the PACE PDP.

B. Procedures

- 1. Any financial or other business arrangements between the PACE PDP and physicians, pharmacies, PBMs, pharmaceutical companies and other health care entities must be structured to comply with all applicable laws and regulations, including the Anti-Kickback Statute and the False Claims Act. If the Compliance Officer or other PACE Organization personnel have questions regarding whether a proposed business arrangement is in compliance with such laws, legal counsel must be consulted to determine whether the proposed arrangement is acceptable.
- 2. When PACE Organization personnel or FDRs are in a position to make referrals or recommendations, they must make such referrals based on the best interests of the Participant and the arrangements the PACE Organization has with contracted providers. PACE Organization personnel and FDRs must not receive anything of value in exchange for making a referral or accepting a referral, or for recommending a health care service provider. In addition, PACE Organization personnel and FDRs must not offer anything of value in order to obtain referrals of patients or services covered under a Federal Health Care Program.

- 3. The following activities are specifically prohibited by PACE Organization, and will not be tolerated within the organization:
 - Submitting false data to CMS for purposes of obtaining reimbursement (including reinsurance and LICS payments) for prescription drugs not dispensed or not provided as claimed, or other costs not incurred as claimed:
 - Submitting data for prescription drug claims that are known not to be reasonable and medically necessary;
 - Intentionally misrepresenting the type of drug that was actually dispensed (e.g., claiming that a brand-name drug was dispensed when in reality a generic was dispensed); and
 - Knowingly submitting data for prescription drugs dispensed to, or obtained by, individuals not eligible for Medicare Part D.
- 4. PACE Organization personnel and FDRs must be trained periodically on these requirements. The Compliance Officer will monitor the Corporate Compliance Hotline for any allegations regarding kickbacks, bribes, or false claims.