

BHS Policies and Procedures



City and County of San Francisco
Department of Public Health
San Francisco Health Network
BEHAVIORAL HEALTH SERVICES

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POLICY/PROCEDURE REGARDING: Conflict of Interest Policy on Interactions between Behavioral Health Services and the Pharmaceutical Industry

Issued By: Maximilian Rocha, LCSW
Director of Systems of Care

Date: 4/12/2023

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Manual Number: 5.00-03

References: California Department of Public Health regulations, 42 CFR Part 2, HIPAA, California Health and Safety Code, Section 123148(f)

Technical Revision: Replaces Policy 5.00-03 dated 9/12/2017

EQUITY STATEMENT:

The San Francisco Department of Public Health, Behavioral Health Services (BHS) is committed to leading with race and prioritizing Intersectionality, including sex, gender identity, sexual orientation, age, class, nationality, language, and ability. BHS strives to move forward on the continuum of becoming an anti-racist institution through dismantling racism, building solidarity among racial groups, and working towards becoming a Trauma-Informed/Trauma Healing Organization in partnership with staff, clients, communities, and our contractors. We are committed to ensuring that every policy or procedure, developed and implemented, lead with an equity and anti-racist lens. Our policies will provide the highest quality of care for our diverse clients. We are dedicated to ensuring that our providers are equipped to provide services that are responsive to our clients' needs and lived experiences.

Purpose:

Behavioral Health Services (BHS) has a duty to provide quality, evidence-based client care, and create a treatment environment that is free from the undue influence of pharmaceutical and device industry manufacturers. This conflict of interest policy addresses the relationship between BHS and the pharmaceutical industry and is intended to prevent conflicts of interest and ensure that selection of medications for BHS clients is based upon objective clinical and scientific evidence. The creation of this policy is also designed to align BHS with recently revised policies from academic medical centers, self-regulated Pharmaceutical Research and Manufacturers of America (PhRMA) guidelines, the Office of Inspector General, San Francisco Conflict of Interest policies, and National Institutes of Health (NIH) guidelines on research.

Scope:

This policy applies to interactions between BHS facilities, BHS staff and all pharmaceutical industries.

BHS facilities include mental health and substance abuse client clinics, programs, urgent care centers, contractors, and individuals who contract with BHS for the provision of services to BHS clients.

BHS staff includes all civil service and BHS-funded program employees including those who are paid, voluntary, or in training.

Pharmaceutical industries include the manufacturers of drugs, medical devices, and biotechnology products, including but not limited to their contractors and affiliates.

Policy:

1. PHARMACEUTICAL INDUSTRY REPRESENTATIVES ACCESS TO BHS FACILITIES

Pharmaceutical industry representatives (PIRs) are not allowed in any client care facility including client treatment areas, waiting rooms, clinic entrances, and other protected care areas. This infringes upon client confidentiality and creates the appearance that a BHS facility is receptive to the commercial interests of pharmaceutical companies.

2. INTERACTIONS BETWEEN PHARMACEUTICAL INDUSTRY REPRESENTATIVES AND BHS STAFF

- a. Pharmaceutical industry representatives are not allowed to contact (including contact by direct in-person visits, telephone, text, email, fax) BHS staff during business hours.
- b. This policy does not prohibit staff from contacting pharmaceutical industry scientific liaisons, medical affairs, quality management or patient assistance programs.
- c. This policy does not prohibit the BHS Medication Use Improvement Committee (MUIC) from engaging industry to provide medical device product training or medical device information for product evaluation. MUIC must provide oversight for all training sessions.

3. GIFTS FROM PHARMACEUTICAL INDUSTRY

- a. Gifts take on many forms including meals, medical education, branded office supplies (notepads, mugs, pens), textbooks, patient handouts, and other items of value. Gifting can influence prescriber behavior by creating a sense of obligation and reciprocity and result in increased prescribing of the company's drugs. A systematic review on gifting and the associated interactions with PIRs (Wazana 2000) found the negative outcomes listed below. A newer study (King 2017) found that policies banning gifts from pharmaceutical companies to doctors were effective in limiting the uptake of new, costly medications.
 1. Inability to identify misinformation
 2. Positive attitude toward PIRs
 3. Preference and rapid prescribing of new drugs
 4. Formulary requests for new drugs without important advantages
 5. Non-rational prescribing behavior
 6. Increased prescription rate of sponsor drugs
 7. Prescribing fewer generics and more branded medications
- b. Material Gifts

PIRs may not offer or provide any material gifts to BHS staff regardless of their nature or monetary value (including pads, pens, mugs, clocks, flowers, candy or other items of nominal value).

c. Meals

Meals constitute a gift and are therefore prohibited at BHS facilities or to BHS staff during working hours. Offsite meals, regardless of time or setting including evenings and weekends, provided by PIRs to BHS employees are strongly discouraged. Regardless of the setting, gifts of meals from a vendor to civil service employees cannot exceed \$25 per occasion and no more than four occasions per year.

d. Educational Grants

Unrestricted education grants for training or other purposes are prohibited.

e. Educational Materials

The use of patient education handouts, medication monitoring forms, side effect assessment tools, software applications, and websites or any other industry sponsored materials constitute gifts and shall not be used by BHS staff or offered to BHS clients.

f. Industry Sponsored Training and Continuing Medical Education

Industry sponsored training with or without the presence of food constitutes a gift and is thus prohibited at BHS facilities or to BHS staff during business hours.

g. Drug Samples and Product Promotion

Drug sampling is a marketing tool that encourages physicians and clients to rely on medications that are expensive, but not necessarily more effective than other available drugs. The long term cost of continuing these medications far outweighs any short term savings. Therefore, drug samples, vouchers or drug specific discount cards are prohibited and cannot be provided to a BHS or affiliated clinic or program.

4. PIRs may not use the BHS name, logo, websites or other BHS identifiers in published materials to promote their products.
5. PIRs may not request, complete or submit drug product addition and/or change requests to the BHS Drug Formulary on behalf of individual BHS clinicians.

6. CONFLICTS OF INTERESTS AND DISCLOSURES

- a. This policy is in addition to any and all existing City and County of San Francisco and Department of Public Health policies on conflicts of interest and vendor relations.
- b. Any BHS staff with influence on the formulary status or purchasing of drugs shall annually disclose interest in pharmaceutical companies or related products including shared interests with a spouse, domestic partner, or other family member. The individual with a conflict of interest must recuse themselves of any decision related to the invested interest.

7. GRANTS AND RESEARCH PROJECTS

Research projects supported in part or whole by grants from the pharmaceutical industry are subject to the research approval procedures delineated in the San Francisco Department of Public Health's privacy policy entitled: "HIPAA Compliance – Privacy and the Conduct of Research." As indicated in the policy, all research, regardless of funding source, must be approved by a duly-constituted Institutional Review Board (IRB) and by the Department of Public Health Director of Ambulatory Care or the Director's designee. Receipt of IRB approval does not guarantee approval from the Department of Public Health, which weighs each request on its merits and grants approval on a case-by-case basis. Research approvals are facilitated by the Director of Quality Management for Behavioral Health Services, to whom research requests should be directed.

8. **NON-COMPLIANCE TO THE POLICY**

- a. Pharmaceutical industry violations of this policy may result in a report to the United States Office of Inspector General and to the San Francisco City Attorney's Office for investigation.
 - b. BHS staff who are determined to have breached this policy will be reported to their supervisor for investigation.
 - c. Staff who are aware of non-compliance to this policy or have any questions concerning the ethics rules for BHS staff can contact the San Francisco County Ethics Commission at (415) 581-2300 or call the Ethics Hotline at (415) 581-2323.
9. Any exceptions to this policy may be requested for review and approval by the BHS Medication Use Improvement Committee (MUIC).

REFERENCES

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