340B DRUG DISCOUNT PROGRAM

- Federal program administered by the Office of Pharmacy Affairs (OPA) under the Health Resources and Services Administrations (HRSA)
- Named for the statute that created it – Section 340B of the 1992 Public Health Services Act (PHS) (GHW Bush)
  - SFGH has participated since 1994
  - Potrero Hill and SE Health Centers have participated since 1995
- Provides outpatient drugs at deeply discounted prices to “covered entities”
  - DPH cost savings estimate: $3 - 4 million / year
DPH Program: 2 Covered Entities

- Retail Pharmacies
- Community Health Centers
- SF Consortium Clinics (#3)
- DPH Primary Care Clinics (#13)
- SFGH Covered SFGH Outpatient Areas (e.g. ED, OR, 4C)
- Eligible SFGH campus clinics
WHO IS ELIGIBLE?

- Organization (covered entity) must be eligible
- Patients must receive health care services from the covered entity (documented in the entity’s medical record)
- Prescriptions must be written by a provider employed by or on contract with the covered entity
- 340B drugs provided to ineligible persons is termed “drug diversion”
WHO BENEFITS FROM THE DPH PHARMACEUTICAL ACCESS PROGRAM?

- **Healthy San Francisco** (> 20 clinics)
- **Un-insured** (including insurance pending)
- **Homeless**
- **Healthy Workers**
340B PROGRAM REQUIREMENTS

- Keep 340B database information accurate
- Recertify eligibility every year
- Prevent diversion to ineligible patients
- Prevent duplicate discounts with Medicaid
- Prepare for program audits
HOW IS COMPLIANCE MONITORED AND ENFORCED?

• Covered entities are subject to audits by manufacturers and HRSA
  • Annual recertification process.
  • HRSA compliance audits.
  • Manufacturer audits (must be approved by HRSA).
• Need to maintain auditable records documenting program compliance
• Penalties may be applied for violating 340B program requirements.
  • Forfeiture of the discounts back to the manufacturer.
  • Removal from the program
SFGH COMPLIANCE MONITORING

- SFGH Audits 9 processes regularly
- Audit compliance dashboard reviewed by leadership
- Selection of “independent auditor” in process
HRSA 340B MEGA-GUIDANCE

HRSA is proposing some significant changes that, if finalized,

- may increase SFGH’s drug expenses
  - Using 340B drugs for discharge prescriptions may be prohibited.

- may further complicate 340B program set-up and compliance
  - Prescriptions written by outside organizations affiliated with a hospital, or written in connection with follow-up care or a referral, would no longer qualify.
COUNTERMEASURES

- Program Compliance Requiring Contract Procurement:
  - Split Billing and 340B compliance software
  - Outpatient pharmacy software
  - 340B independent auditor
  - Evaluate program set-up
PLANNED IMPROVEMENTS

• Partnership with new Third Party Administrator (Walgreens)
• Expand Pharmacy Network
• Expand populations served (e.g. Medicare)