

340B INDEPENDENT AUDITOR
FOR DEPARTMENT OF PUBLIC SAFETY'S HEALTH CARE DIVISION
PSD 23-HCD-32

Background

The Department of Public Safety (PSD), State of Hawaii, is a registered 340B covered entity as an STD clinic, section 318 subgrantee, through an MOA with the Hawaii Department of Health. PSD has NOT implemented the 340B program; PSD is pending completion of account activation with the wholesaler and completion of the actions in this request for quote (described below) prior to implementation. PSD has a ship-to/bill-to set up (340B contract) with the contract pharmacy and wholesaler. PSD does not bill Medicaid. The 340B policies and procedures have been drafted. The system of documentation, notification of provider and patient eligibility, forms, process for patient eligibility verification, plan for physical separation of 340B drugs from non-340B drugs, internal audit process, and other relevant actions are being addressed. Four of our 340B Oversight Committee members completed the Apexus online training and two members attended the in-person basic 340B University training.

PSD operates four (4) jails and four (4) prisons on four (4) islands:

a) Oahu

- Halawa Correctional Facility (HCF)
99-902 Moanalua Rd
Aiea, HI 96701

- Oahu Community Correctional Center (OCCC)
2199 Kamehameha Hwy
Honolulu, HI 96819

- Women's Community Correctional Center (WCCC)
42-477 Kalaniana'ole Hwy
Kailua, HI 96734

- Waiawa Correctional Facility (WCF)
94-560 Kamehameha Hwy
Waipahu, HI 96797

b) Hawaii

- Hawaii Community Correctional Facility (HCCC)
60 Punahele St
Hilo, HI 96720

- Kulani Correctional Facility (KCF)

HC 01, Stainback Hwy
Hilo, HI 96720

c) Maui

- Maui Community Correctional Facility (MCCC)
600 Waiale Rd
Wailuku, HI 96720

d) Kauai

- Kauai Community Correctional Facility (KCCC)
3-5351 Kuhio Hwy
Lihue, HI 96766

Scope of Work

The Department of Public Safety (PSD), State of Hawaii, seeks a 340B Independent Auditor to conduct an initial on-site evaluation of the PSD 340 Program prior to implementation and to conduct an onsite (i.e., at one facility listed above selected by PSD) independent audit after six (6) months of implementation. The comprehensive 340B program review must include subject matter expert (SME) insights on compliance risk and gap analysis with corrective action reports, program development support to ensure 340B program compliance prior to implementation, and monthly 340B program compliance support from a 340B SME. The six (6) month post-implementation external audit must simulate an onsite Health Resources and Services Administration (HRSA) audit. Comprehensive audit procedures should demonstrate best practices, meet or exceed national standards, and include, at a minimum:

- Review of relevant policies and procedures and how they are operationalized;
- Review and maintenance of required auditable records;
- Verification of eligibility;
- Accuracy of Office of Pharmacy Affairs Information System (OPAIS) database registration for covered entity and contract pharmacy;
- Review of 340B Program compliance at covered entity, outpatient or associated facilities, and contract pharmacies;
- Verification of internal controls to prevent diversion and duplicate discounts, including how the covered entity defines whether a patient is considered eligible, and accuracy of covered entity's 340B database record;
- Drug procurement processes and adherence to provider, site, and patient eligibility criteria;
- Contract Pharmacy compliance;
- Testing of 340B drug transaction records on a sample basis;
- Review of internal audit procedures and checklist; and
- Recommendations to incorporate industry-standard best practices.

The auditor must provide a detailed technical report; methodologies employed, vulnerability findings with risk ratings. Other recommendations will include a corrective action plan to include immediate and long-term steps for remediation, necessity of a self-disclosure, and a plan for on-going preventative strategies/education/auditing within 60 days of audit completion.

PSD also requires 340B Monthly Maintenance, which must include dedicated staff to provide remote compliance consulting for up to 2 hours per month and, in the event of a formal HRSA 340B audit, remote audit support staff availability for the duration of the HRSA 340B audit.

Minimum Qualifications

The proposer must meet the following minimum qualifications in order to participate in this request for quote:

1. Respondent shall have five (5) years of experience conducting Annual 340B Independent Audits.
2. Respondent must have completed at least 100 independent audits within the past year.
3. Respondent must be able to conduct on-site audits.

Unit Bid Price/Quote

The requested unit bid price must include the cost for all services identified above, including travel expenses for the initial program evaluation and mock HRSA independent audit. The quoted unit price shall be the all-inclusive cost to the State (i.e. all taxes, on-site travel fees, etc.), and no other charges will be honored.

Term of Services: Two Years from the Start Date of the Notice to Proceed.

Options to Extend: May be extended for three additional twelve-month periods or portion thereof, upon prior mutual agreement, and subject to availability of funds.

Payment

The Contract shall invoice upon successful completion of the work described herein, no requests for pre-payment shall be permitted. Contractor will be compensated in full for each service provided in accordance with the terms and conditions of the resultant Agreement. Contract shall reference the contract number PSD 23-HCD-32 on all invoices for payment. Section 103-10, HRS, provides that the State shall have thirty (30) calendar days after satisfactorily delivery of goods and receipt of invoice to make payment. For this reason, the State will reject any offer submitted with a condition requiring payment within a shorter period. Further, the State will reject any offer submitted with a condition requiring interest payments greater than that allowed by Section 103-10, HRS, as amended.

The State will not recognize any requirement established by the Contractor and communicated to the State after award of the contract, which requires payment within a shorter period or interest payment not in conformance with statute.

No payment, whether partial or final, shall be construed to be an acceptance of a defective or unacceptable product.

Final Payment Requirements. If the Contractor is currently registered in HCE, the Contractor is required to submit a valid "Certificate of Vendor Compliance" for final payment on the contract. Otherwise, valid hard copies of the tax clearance certificate (not more than two months old).

Award

Award shall be made to the qualified responsive and responsible Offeror submitting the lowest Total Sum Bid on Offer Form Page OF-3.

Offer Submittal Instructions

Offer Form Pages, OF-1 through OF-3 must be submitted.

Failure to submit the above referenced forms with your bid submittal may result in the rejection of your offer.

Insurance Requirements

The Contractor shall maintain insurance acceptable to the State in full force and effect throughout the term of this contract. The policy or policies of insurance maintained by the Contractor shall provide the following limit(s) and coverage:

Coverage	Limits
Commercial General Liability (occurrence form)	\$1,000,000 per occurrence for bodily injury and property damage \$2,000,000 aggregate
Comprehensive Automobile Liability	\$1,000,000 per accident

Each insurance policy required by this contract shall contain the following clauses:

1. "The State of Hawaii, Department of Public Safety, is added as an additional insured as respects to operations performed for the State of Hawaii."

2. "It is agreed that any insurance maintained by the State of Hawaii will apply in excess of, and not contribute with, insurance provided by this policy."

Each insurance policy shall be written by insurance companies licensed to do business in the State or meet Section 431:8-301, HRS, if utilizing an insurance company not licensed by the State of Hawaii.

The Contractor agrees to deposit with the State of Hawaii, on or before the effective date of this contract, certificate(s) of insurance necessary to satisfy the State that the insurance provisions of this contract have been complied with and to keep such insurance in effect and the certificate(s) thereof on deposit with the State during the entire term of this contract. Upon request by the State, Contractor shall furnish a copy of the policy or policies.

Failure of the Contractor to provide and keep in force such insurance shall be regarded as material default under this contract, entitling the State to exercise any or all of the remedies provided in this contract for a default of the Contractor.

The procuring of such required policy or policies of insurance shall not be construed to limit Contractor's liability hereunder nor to fulfill the indemnification provisions and requirements of this contract. Notwithstanding said policy or policies of insurance, Contractor shall be obliged for the full and total amount of any damage, injury, or loss caused by negligence or neglect connected with this contract.