**Instructions:** This tool contains a checklist of considerations for covered entity leaders when developing a request for proposal (RFP) document to solicit independent 340B compliance audit proposals.

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| **Considerations** | **Completed** |
| 1. Entity leadership will determine specific proposal components. Consider including a cover letter that outlines the purpose of solicitation, expectations and general provisions for proposal submission, award criteria, and the scope of 340B operations included in the audit request. |  |
| 2. RFP Section 1. Audit firm overview   1. Firm’s industry competence and specialization in 340B and/or pharmacy auditing 2. Firm’s experience in serving other 340B covered entities, noting those that have undergone  a HRSA audit and the audit findings 3. Corporate references |  |
| 3. RFP Section 2. Audit team qualifications   1. Qualifications and relevant experience, including biographies of staff who would be assigned to the project 2. 340B-specific staff training (including 340B University OnDemand completion, 340B University live session attendance, continuing education, and other relevant proficiencies) 3. Experience working with similar 340B covered entity types 4. Level of involvement of key partners and managers |  |
| 4. RFP Section 3. Audit methodology and project management   1. Specific areas of focus, including how each item is addressed under the audit approach 2. Detailed testing procedures of each audit phase 3. Eligibility, diversion, duplicate discount, inventory/record-keeping, 340B OPAIS record, standard operating procedures, etc. 4. Methods used to manage the overall project and client correspondence 5. Breakdown of engagement expectations on-site and off-site 6. Detailed descriptions of data needed for the audit |  |
| 5. RFP Section 4. Findings and recommendations at the audit conclusion   1. Detailed technical report; methodologies employed, and a risk assessment for each finding 2. Corrective action plan to include immediate and long-term steps for remediation, necessity of a self-disclosure, and a plan for ongoing preventive strategies/education/auditing |  |
| 6. Entity leadership may choose to evaluate submitted bids based on the level and robustness of  audit procedures that assess compliance standards included in [PVP education tools website](https://www.340bpvp.com/education/340b-tools/)  (see “Auditing and Compliance” section for your CE type). One example is the [Self-Audit: Policy and Procedure](https://docs.340bpvp.com/documents/public/resourcecenter/self-audit-policy-and-procedure.docx) tool. |  |

*These tools, written to align with Office of Pharmacy Affairs (OPA) policy, are provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by OPA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages each stakeholder to include legal counsel as part of their program integrity efforts.*

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