



# 340B Independent Audit Request for Proposal (RFP) Checklist

Instructions: This tool is designed to provide entity leaders a checklist of action items to consider when developing a Request for Proposal (RFP) document to solicit proposals from external organizations to conduct 340B compliance audits on behalf of the covered entity, and in order to promote program integrity.

Tool	Completed
1. Entity leadership will determine specific proposal component requirements. Entity may consider including a cover letter that outlines purpose of solicitation, expectations and general provisions for proposal submission, award criteria, and the scope of 340B operations that are included in the audit request.	
2. RFP Section 1. Audit firm overview <ul style="list-style-type: none"> <li>▪ Firm’s industry competence and specialization in 340B and/or pharmacy auditing business</li> <li>▪ Firm’s experience in serving other covered entities, noting those of which have undergone a HRSA audit and results</li> <li>▪ Corporate references</li> </ul>	
3. RFP Section 2. Audit engagement team qualifications <ul style="list-style-type: none"> <li>▪ Qualifications and relevant experience of the types of staff that would be assigned to the project with sample biographies</li> <li>▪ 340B-specific ongoing training conducted for team (including 340B University attendance, 340B Continuing Education, relevant proficiencies, etc.)</li> <li>▪ Level of involvement of key partners and managers</li> </ul>	
4. RFP Section 3. Audit methodology and project management <ul style="list-style-type: none"> <li>▪ Specific risks and areas of focus, including how each is addressed under the audit approach</li> <li>▪ Detailed testing procedures of each audit phase               <ul style="list-style-type: none"> <li>– Eligibility, diversion, duplicate discount, inventory/record-keeping, HRSA database record, standard operating procedures (SPOs)</li> </ul> </li> <li>▪ Method and approach used to manage the overall project and client correspondence</li> <li>▪ Breakdown of engagement time expectations on-site and off-site</li> <li>▪ Detailed descriptions of data needed by audit firm</li> </ul>	
5. RFP Section 4. Audit findings and recommendations at the conclusion of the assessment <ul style="list-style-type: none"> <li>▪ Detailed technical report; methodologies employed, vulnerability findings with risk ratings</li> <li>▪ 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</li> </ul>	
6. Entity leadership may choose to evaluate submitted bids on level and robustness of audit procedures that assess compliance standards included in the following Apexus tools: <ul style="list-style-type: none"> <li>▪ 340B Policy Compliance [choose appropriate tool based on covered entity type]:               <ul style="list-style-type: none"> <li>– <a href="#">340B Audit Tool for DSH Hospitals</a></li> <li>– <a href="#">340B Audit Tool for Rural Hospitals</a></li> <li>– <a href="#">340B Audit Tool for Health Centers</a></li> </ul> </li> <li>▪ Contract Pharmacy Audits: <a href="#">340B Compliance Self-Assessment of Contract Pharmacy Vendors</a></li> </ul>	

*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 the 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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