

HRSA 19 Program Requirements			Recommendations to satisfy 340B, HRSA & FTCA		
<i>The measures listed below are the 19 Program Requirements for HRSA Grantees</i>			<i>The following actions will best satisfy 340B</i>		<i>The following actions will best satisfy FTCA (FTCA Category)</i>
FQHCs must meet all 19 Requirements					
Section I:	Need				
1.	Needs Assessment: health center has a documented assessment of the needs of its target population, and has updated its service area when appropriate				
Section II:	Services				
2.	Required and additional services: health center provides all required primary, preventative, and enabling health services and provides additional health services as appropriate and necessary, either directly or through established written arrangements and referrals	Written referral or contractual agreement with providers outside of the covered entity (i.e. Specialty providers) who may prescribe medications to patients to make sure patient eligibility requirements are fulfilled. Include agreements, verification process and documentation tools in policy and procedures manual		Board approved policy and procedure must be in place to track patient referrals (RT)	
3.	Staffing: health center maintains a core staff as necessary to carry out all required primary, preventative, enabling health services and additional health services as appropriate and necessary, either directly or through established arrangements and referrals. Staff must be appropriately licensed, credentialed and privileged.	All staff who touch 340B program should have documented training and education at least annually. Documents should be included in policy and procedures manual.		Health Center staff must be licensed, credentialed and privileged. There must be Board approved policies and procedures in place for accurate and timely credentialing and privileging. (CL)	

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<p>4. Accessible hours of operation/locations: health center provides services at times that assure accessibility and meet the needs of the population to be served. Health center provides services at locations that assure accessibility and meet the needs of the population to be served.</p>	<p>Make sure all locations that are dispensing 340B medications are accurately registered in the OPA database.</p>	<p>Providers of care in all health center sites must be credentialed and privileged in the same manner. (CP)</p>

<p>5. After Hours Coverage: health center provides professional coverage for medical emergencies during hours when the center is closed</p>		
<p>6. Hospital admitting privileges and continuum of care: health center physicians have admitting privileges at one or more referral hospitals, or other such arrangement to ensure continuity of care. In cases where hospital arrangements (including admitting privileges and membership) are not possible, the health center must firmly establish arrangements for hospitalization, discharge planning, and patient tracking.</p>	<p>Keep accurate and updated physician eligibility list to ensure that 340B prescriptions are only given by eligible providers. Include eligibility list in policy and procedures manual as well as document how often list is updated, who it is shared with and process for checking physician eligibility when filling 340B prescriptions.</p>	<p>Agreements must be in place for continuum of care for hospitalized patients. This includes policies and procedures for discharge planning along with patient tracking. (HT)</p>
<p>7. Sliding Fee Discounts: health center must assure that no patient will be denied services due to their inability to pay for such services. Health center has a system in place to determine eligibility for patient discounts adjusted on the basis of the patient's ability to pay.</p>	<p>Have readily available Medicaid Exclusion file to show carve-in or carve-out status.</p> <p>Include 340B dispensing process for FFS, managed care, and uninsured patients. Clearly define sliding fee scale criteria if utilize for 340B patients</p> <p>Maintain updated and accurate documents of above information in the policy and procedures manual</p>	
<p>8. Quality Improvement/Assurance Plan: health center has an ongoing Quality Improvement/Quality Assurance (QI/QA) program that includes clinical service and management, maintains the confidentiality of patient records, includes a clinical director whose focus</p>	<p>Have a self-audit, internal control process that is used to audit patient records who are receiving 340B medications. Work with IT to ensure software is capturing correct patient data. Perform periodic assessment of utilization of services and in-house/contract pharmacy practices.</p>	<p>The health center Quality Plan must include peer review for all providers and be approved by the health center Board. (QP) (DT)</p>

<p>of responsibility is to support the QI/QA program and the provision of high quality patient care, and includes periodic assessment of the appropriateness of the utilization of services and the quality of services provided or proposed to be provided to individuals served by the health center.</p>	<p>Include workflows and processes in policy and procedures manual.</p>	
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<p>Section III:</p>	<p>Management and Finance</p>		
<p>9.</p>	<p>Key Management Staff: health center maintains a fully staffed health center management team as appropriate for the size and needs of the center.</p>	<p>C-Suite and Mid-Management understand and know their roles in the 340B program</p>	
<p>10.</p>	<p>Contractual/Affiliation Agreements: health center exercises appropriate oversight and authority over all contracted services</p>	<p>Accurate and updated contract pharmacy agreements are readily available with contact information, addresses, all locations are listed.</p> <p>Contracted physicians agreements are accurate and outline stipulations of ability to prescribe 340B medications to patients.</p> <p>Maintain accurate and updated documentation of processes in policy and procedures manual.</p>	

<p>11.</p>	<p>Collaborative Relationships: health center makes effort to establish and maintain collaborative relationships with other health care providers,</p>	<p>See Requirement 6</p>	
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<p>including other health centers, in the service area of the center. Health center secures letters of support from existing health centers (section 330 grantees and FQHC look-alikes) in the service area or provides an explanation for why such letter(s) of support cannot be obtained</p>		
<p>12. Financial Management and Control Policies: health center maintains accounting and internal control systems that are appropriate to the size and complexity of the organization, reflect Generally Accepted Accounting Principles (GAAP), separate functions in a manner appropriate to the organization's size in order to safeguard assets and maintain financial stability. Health center assures that an annual independent financial audit is performed in accordance with Federal audit requirements and a corrective action plan addressing all findings, questioned costs, reportable conditions, and material weaknesses cited in the Audit Report is submitted.</p>	<p>Have internal control process:</p> <ul style="list-style-type: none"> • Independent auditor • Self-Auditing <p>Clearly state how often audit process occurs and keep a log of findings (if any complete self-disclosure and submit to OPA)</p> <p>Track and manage inventory/replenishment in in-house/contract pharmacies review reports for correct any negative balances</p> <p>Self-audit monthly if possible. Annually is the suggested by OPA/HRSA</p> <p>Maintain self/independent audit records in policy and procedures</p>	

<p>13. Billing and Collections: health center has systems in place to maximize collections and reimbursement for its costs in providing health services</p>		
<p>14. Budget: health center has developed a budget that reflects the costs of operations, expenses, and revenues (including the Federal grant) necessary to accomplish the service delivery plan, including the number of patients to be served</p>		
<p>15. Program Data Reporting System: health center has systems in place which, accurately collect and organize data for program reporting and support management decision making</p>		
<p>16. Scope of Project: health center maintains its funded scope of project (sites, services, service area, target population and providers), including any increases based on recent grant awards</p>	<p>See Requirement 1</p>	
<p>Section IV: Governance</p>		

<p>17. Board Authority: health center governing board maintains appropriate authority to oversee the operations of the center, including: holding monthly meetings, approval of health center grant application and budget, selection/dismissal and performance evaluation of the health center CEO, selection of services to be provided and the health center hours of operations, measuring and evaluating the organization's progress in meeting its annual and long-term programmatic and financial goals and developing plans for the long-range viability of the organization by engaging in strategic planning, ongoing review of the organization's mission and bylaws, evaluating patient satisfaction, and monitoring organization assets and performance, and establishment of general policies for the health center.</p>	<p>Develop 340B team that meets regularly to review program requirements and updates</p>	<p>The health center Board must approve privileging and re-privileging of all providers. (CP)</p> <p>The Quality Plan must be Board approved. (QI)</p>
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<p>18. Board Composition: the health center's governing board meets the following requirements: a majority of the board members are individuals served by the organization, as a group, these "patients" or "consumer" board members represent the individuals being served by the health center in terms of demographic factors such as race, ethnicity, and sex. The board has at least 9, but no more than 25 members, as appropriate for the complexity of the organization. The remaining non-consumer board members shall be representative of the community in which the center's service area is located and shall be selected for their expertise in community affairs, local government, finance and banking, legal affairs, trade unions, and other commercial and industrial concerns, or social service agencies within the community. No more than half (50%) of the non-consumer board members may derive more than 10% of their annual income from the health care industry.</p>		

19.

Conflict of Interest Policy: health center's bylaws or written, corporate-board-approved policy includes provisions that: prohibit conflict of interest by board members, employees, consultants and those who furnish goods or services to the health center, state that no board member shall be an employee of the health center or an immediate family member (i.e., spouse, child, parent, brother or sister by blood, adoption or marriage) of an employee, state that the Chief Executive may serve only as a non-voting, ex-officio member of the board, and will address such issues as: disclosure of business and personal relationships, extent to which board members can participate in board decisions where the member has a personal or financial interest, using board members to provide services to the center, board member expense reimbursement policies, acceptance of gifts and gratuities, personal political activities of board members and, statement of consequences for violating the conflict policy.