

Compliance Program Standards (All service lines)

[HH, H, HIT, pharmacy, DME, HC]

KPA – Compliance Program

Standard	Evidence
The organization has a compliance program with a designated officer and committee who are responsible for its operation.	<p>Document review: Review the organization’s written compliance program.</p>
<p>The designated compliance officer/staff member and compliance committee are responsible for the following key compliance program duties:</p> <ul style="list-style-type: none"> • Maintaining regulatory knowledge and monitoring regulatory compliance • Staff education • Identifying organizational compliance gaps • Facilitate regular compliance meetings • Participating in organizational policy review and update to ensure relevant regulatory updates as applicable • Preparation of compliance information for the governing board • Ensuring ethical marketing practice 	<p>Document review: Review the job duties of the compliance officer/staff member to validate duties outlined in the standard are included.</p> <p>Review job duties and evidence of education of designated compliance officer and compliance committee are completed.</p> <p>Interview: Interview designated compliance staff to determine their role and understanding of compliance program duties.</p> <p>Tips: Compliance officers may also have another position title and duties in addition to compliance management.</p> <p>In smaller organizations, this may be the QAPI committee, IDG, or other group. Compliance policy should outline who serves on the organization’s compliance committee.</p>
<p>The organization has written compliance policies and procedures and standards of conduct that are:</p> <ul style="list-style-type: none"> • relevant to day-to-day responsibilities • available to those who need them • re-evaluated regularly 	<p>Document review: Review the organization’s written compliance program policies and procedures and standards of conduct to determine they are relevant to day-to-day responsibilities, available to those who need them, and re-evaluated regularly.</p> <p>Interview: Interview staff members with various positions in the organization to determine if they know about the compliance policies and procedures and standards of conduct and where to find them.</p>

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The organization has a mechanism for reporting instances of potential compliance issues and makes the information available to staff members.	<p>Document review: Review the organization's written compliance program to determine the reporting mechanism established so that staff members can report potential compliance issues.</p> <p>Interview: Interview staff members with various positions in the organization to determine if they know about the mechanism to report potential compliance issues.</p>
The organization has an effective auditing and monitoring plan in place to detect compliance issues.	<p>Document review: Review the organization's auditing and monitoring plan to ensure it is active.</p> <p>Interview: Interview designated compliance staff to assess their awareness of the organization's auditing and monitoring activities.</p>
The organization documents investigation of compliance issues, implementation of corrective action, and periodic review of the problem to ensure compliance.	<p>Document review: Review the organization's investigative process and corrective compliance action plans to determine if they were implemented and reviewed to verify the corrective action that was implemented was successful.</p> <p>Review documentation of investigation of compliance issues, implementation of corrective action, and periodic review of the problem to ensure compliance.</p> <p>Interview: Interview the compliance officer (or equivalent position) to assess the investigation process, corrective action implementation, and follow-up to determine success.</p>
The organization emphasizes ethical behavior by enforcing standards of conduct, consistently applying staff disciplinary guidelines, and checking employees, contractors, and medical and clinical staff members routinely against	<p>Document review: Review the organization's documentation for:</p> <ol style="list-style-type: none"> 1. enforcing standards of conduct; 2. publicizing and applying disciplinary guidelines; and

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government sanctions lists, including the OIG's List of Excluded Individuals/Entities.	<p>3. checking employees, contractors and medical and clinical staff members monthly against government sanctions lists, including the OIG's List of Excluded Individuals/Entities.</p> <p>Interview: Interview staff members to determine their understanding of the organization's expectations for ethical conduct and their awareness of disciplinary guidelines.</p>
<p>The organization educates new staff and contractors at orientation and annually about their compliance program.</p> <p>All staff, whether employed directly or under arrangement, participate in organization-sponsored in-service programs about actual and potential compliance issues and regulatory updates as applicable.</p>	<p>Document review: Review the organization's orientation and continuing education to confirm education about the written compliance program was provided.</p> <p>Verify that the individuals participated in in-service training. This information may be maintained in education records separate from the personnel file.</p>