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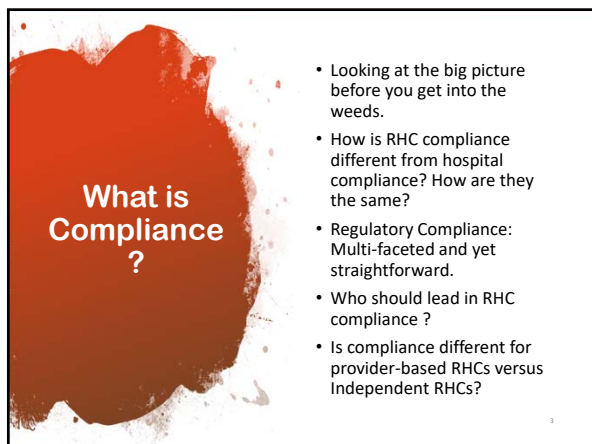
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Let's make it simple: Government control means uniformity, regulation, fees, inspection, and yes, compliance. --Tom Graves

Healthcare is a regulated industry.

The framework for compliance already exists.

Don't re-invent the wheel. Use what we already know. And if we don't know, learn and teach!

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Compliance can include all these areas.

- HHS Regulatory Compliance
  - CMS Conditions of Participation
  - CMS RHC Conditions for Certification 42 CFR §491
  - CMS Guidance (IOMs and Appendices)
  - Office of Civil Rights/HIPAA
  - OIG Enforcement
- Other Federal Laws
  - Labor Laws
  - OSHA
- State Laws
- Local Laws (County and City)

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Where do you start ?

It can be overwhelming to either create or revamp a compliance plan.

What is needed for RHC Certification may be different from what is need for the parent organization or to meet other regulations.

What is needed for RHC Certification is not everything needed for regulatory compliance.

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**Use the regulations as a compliance blueprint.**

- Would you plan a house without a blueprint?
- Would your contractor build the house without ever looking at the plans?
- Federal, State and Local Regulations are the blueprint for any type of facility's compliance.

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**Federal RHC/FQHC Regulations**

**42 CFR §491  
Conditions for certification**

**42 CFR §405  
Subpart X**

**42 CFR §413.65  
Provider Based Status**



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**Federal Hospital Regulations**

**42 CFR §482  
Conditions of Participation**

**42 CFR §412  
Inpatient PPS System**

**42 CFR §419  
Outpatient PPS System**



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**Federal Regulations  
Critical Access  
Hospitals**

**42 CFR §485  
Subpart F  
Conditions of  
Participation**



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**Federal Regulations  
Medicare Program**

**42 CFR §405  
Federal Healthcare for  
the Aged and Disabled**

**42 CFR §420  
Program Integrity-  
Medicare**

**42 CFR §455  
Program Integrity-  
Medicaid**



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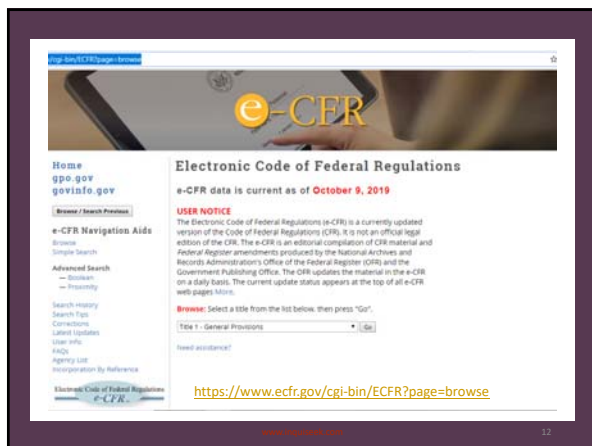
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The screenshot shows the e-CFR website with the following content:

- Header: e-CFR
- Section: Electronic Code of Federal Regulations
- Status: e-CFR data is current as of **October 9, 2019**
- USER NOTICE: The Electronic Code of Federal Regulations (e-CFR) is a currently updated version of the Code of Federal Regulations (CFR). It is not an official legal edition of the CFR. The e-CFR is an editorial compilation of CFR material and Federal Register amendments produced by the National Archives and Records Administration's Office of the Federal Register (OFR) and the Government Publishing Office. The OFR updates the material in the e-CFR on a daily basis. The current update status appears at the top of all e-CFR web pages.
- Navigation: Home, gpo.gov, govinfo.gov, Browse / Search Provisions
- Search Options: e-CFR Navigation Aids, Simple Search, Advanced Search (Boolean, Proximity), Search History, Search Tips, Corrections, Latest Updates, User Info, FAQs, Agency List, Incorporation By Reference.
- Footer: <https://www.ecfr.gov/cgi-bin/ECFR?page=browse>

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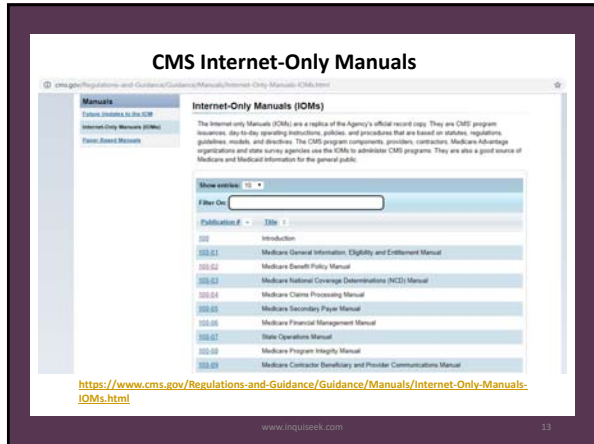
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**Develop Written Policies based on your regulatory blueprints**

- Written policies are required for RHC Conditions of Certification
- Written policies are needed to meet Conditions of Participation
- A formal Compliance Plan to prevent fraud, waste and abuse is needed.
- Accreditation Organizations may have other requirements.

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**Tips for Policy Development**

- Don't make policy writing more difficult than it needs to be. More is not more!
- Use broad language that established compliance without locking you into a rigid process or procedure that might change.
- Organize policies topically or in the order of the survey tags or standards.
- Policies should not be used to manage people but to ensure practical compliance.

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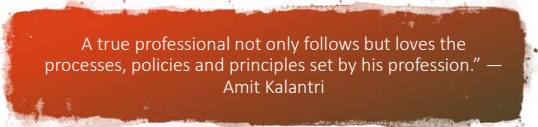
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*"A true professional not only follows but loves the processes, policies and principles set by his profession." — Amit Kalantri*

**Policies** are broad statements of compliance which are static unless there is a regulatory change. Less is More.

**Processes** are more defined by nature are dynamic. They are usually created internally or in conjunction with other guidance. Provide Clarity. Can Be addendums or supplemental documents.

**Procedures** are specific steps in performing a task. These are dynamic, promote efficiencies in workflow and ensure quality performance. Used for training and internal guidance. Promotes standardization of tasks.

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**“What can be asserted without evidence can also be dismissed without evidence.”**  
— Christopher Hitchens

Proof of compliance especially during a survey can be difficult if supporting “evidence” documents are not easy to retrieve.

Correlate supporting evidence to policy numbers or to survey tags or standards.

Refer to the SOM Appendices or the AO guidance to determine what might be needed.

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**Examples of Evidence Documents**



- Licenses
- Certificates
- Inspection Reports
- Correspondence to/from CMS/Medicare Contractor
- Correspondence to/from state agencies
- Other Agency Correspondence
- Quality, QAPI, and Risk Documents and Forms
- Samples of Notices and Disclosures
- Proof of Education and Training

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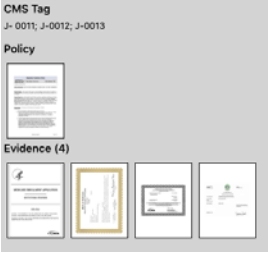
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**Identify Supporting Evidence Documents and Keep them Up-to-Date**



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“Wasted strokes, like missed deadlines, are preventable and costly.”  
 — Lorii Myers

Some policy or document management systems have a built-in tickler function.

Spreadsheets, calendars or tickler organizers can all work. Create a format that works for you and your facility.

Set reminders far enough in advance to allow for processing time, approval time, or scheduling.

Build-in accountability so that more than one person is aware of a deadline. [www.inquireseek.com](http://www.inquireseek.com)

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**TICKLER LIST**

Date	Subject	Assignment
01/01/20	250-C Replace Declaration Sheet on Insurance Website	250-C_Insurance_HealthPlan_AL_01/01/20
01/01/20	260-A Verify contractors are within time zone	260-A_Contractors_Contractors_AL_01/01/20
01/01/20	270-A Review all cleaning contracts	270-A_Cleaning_and_Maintenance_Services_AL_01/01/20
01/01/20	280-A Review the Fire Review Authorization Form	280-A_Fire_Review_Authorization_Form_AL_01/01/20
01/01/20	290-A Verify current Employment Agreements	290-A_Employment_Agreements_AL_01/01/20
01/01/20	300-A Review the CNA's Annual Evaluation	300-A_CNA_Annual_Evaluation_AL_01/01/20
01/01/20	310-A Review the CNA's Annual Evaluation	310-A_CNA_Annual_Evaluation_Texas_AL_01/01/20
01/01/20	320-C Verify current Training Schedule	320-C_Training_Schedule_AL_01/01/20
01/01/20	330-A Update Employer Return	330-A_Employer_Return_AL_01/01/20
01/01/20	340-A Review Temperature and Disinfectants	340-A_Temperature_and_Disinfectants_AL_01/01/20
01/01/20	350-A Update safety temperature logs with current temperature logs	350-A_Safety_Temperature_Logs_AL_01/01/20
01/01/20	360-A Review state license. A check will be required. 0001 8000	360-A_State_License_AL_01/01/20
01/01/20	370-A Review State License and Register are correct	370-A_State_License_and_Register_AL_01/01/20
01/01/20	380-A Review BSA to make sure the policies on the BSA are still in the same form	380-A_BSA_Policies_AL_01/01/20
01/01/20	390-A Update Emergency Preparedness Plan, Procedures	390-A_Emergency_Preparedness_Plan_Procedures_AL_01/01/20
01/01/20	400-A Update Safety and Health Manual	400-A_Safety_and_Health_Manual_AL_01/01/20
01/01/20	410-A Review - Update Current Forms	410-A_Current_Forms_AL_01/01/20
01/01/20	420-C Verify Medication Rubric Bulletin is on the wall in the Nursing Station	420-C_Medication_Rubric_Bulletin_AL_01/01/20
01/01/20	430-A Verify current Inspections	430-A_Inspections_Schedule_Alignment_and_Schedule_AL_01/01/20

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**Examples of Tickler Dates**



- Licenses Renewals
- Inspections
- Required Employee Training
  - Periodic
  - Annual Education Fair
- Policy Review Dates
- Program Evaluation Dates
- Performance Evaluations
- Updated Employee Forms
- Emergency Preparedness Testing/Training
- Employee Health
- **Anything that a policy specifically states will require review or retraining.**

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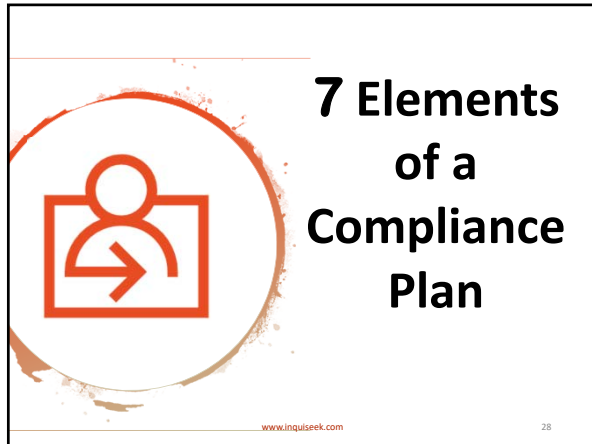
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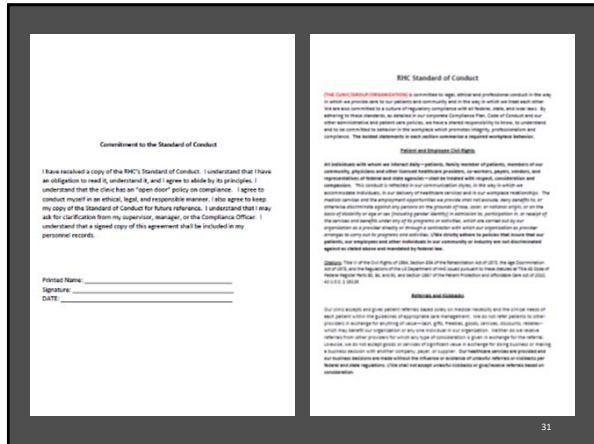
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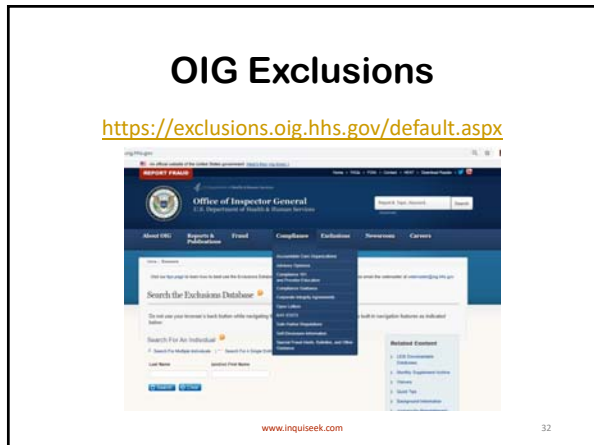
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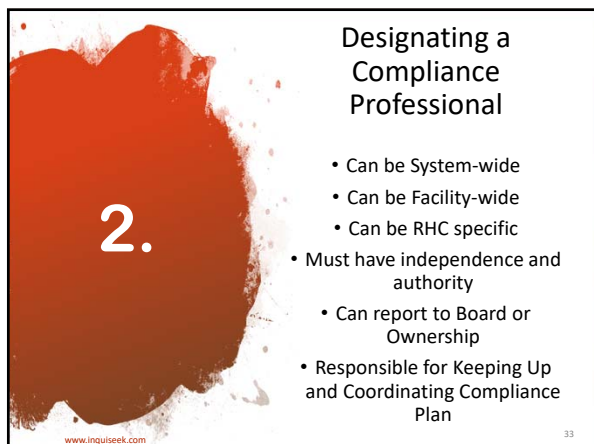
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### 3. Open Communication

- Open Door Policy
- Hotlines
- Complaint Boxes
- Non-retaliatory Policy (Really?)
- Culture of Compliance and Communication

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### 4. Training and Education

- Fraud, Waste and Abuse
- Quality of Care
- Policies, Processes and Procedures
- Roles and Responsibilities

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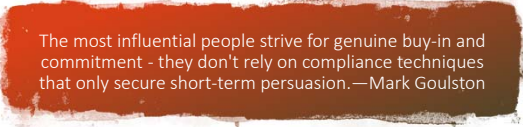
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The most influential people strive for genuine buy-in and commitment - they don't rely on compliance techniques that only secure short-term persuasion.—Mark Goulston

- Create Buy-in by engaging all staff.
- Substance Over Form; Be creative and interactive.
- Have a training schedule: on hire, whenever there is a change, and periodically thereafter. Facilitate training and engagement.
- Make training specific to role or department
- Obtain feedback from staff.
- Document Training

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**5.**

### Respond Promptly to Concerns and Incidents of Non-Compliance

- Take all concerns seriously
  - Have a process for investigation
  - Internal v. External

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**6.**

### Conducting Monitoring and Auditing

Monitoring is Internal  
Auditing is External

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### Examples of Auditing and Monitoring

- Coding and Billing Reviews (internal/external)
  - Accuracy
  - NCCI Edits
  - Medical Necessity
- Revenue Cycle Functions/Checks & Balances
- Clinical Documentation
- Professional Services Contracts and Employment Agreements
- Medical Staff Functions
- Standard of Care

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## Enforce Disciplinary Actions

- Established policies
- Consistency
- Retraining
- Consequences
- Self Reporting

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## 7 Elements of a Compliance Plan

- Implementing Compliance Standards
- Designating a Compliance Professional
- Open Communication
- Training and Education
- Respond Promptly to Concerns and Incidents of Non-Compliance
- Conducting Monitoring and Auditing
- Enforce Disciplinary Actions

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## Keeping Compliance Relevant

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### Where do we go wrong?

- We fail to create a culture of compliance.
- We reduce compliance to an HR checklist or we have form over substance.
- We make policies too complex and difficult to follow.
- We distance the compliance function from daily operations.
- We don't stay current with regulations, policy maintenance or education.
- We assume that everyone knows what to do.

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### Compliance is both static and dynamic!

- Redesign your blueprint as needed
- Keep training methods fresh
- Retool monitoring when you have operational changes
- Balance responsibility and authority

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**"To be relevant, you need to be purposeful"**  
— Sunday Adelaja

Don't assume that the written policies or compliance plan you inherited are up-to-date or complete. Even corporate level policies can fail to meet compliance especially when rural health providers are scarce within the system.

Don't wait for a survey deficiency or a payer audit to reveal a gap in compliance.

Revise and Simplify—making sure that the policies and training are following the regulatory blueprint.

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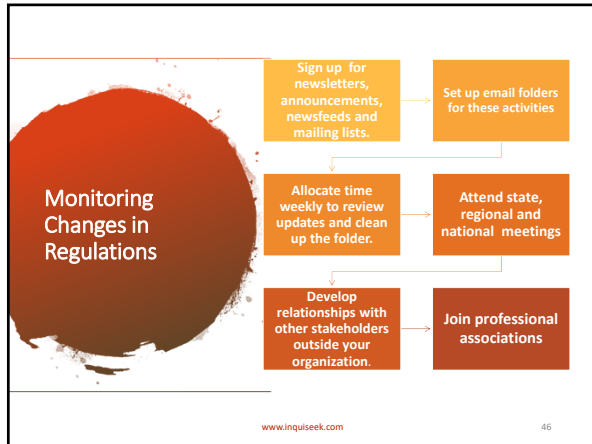
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### Resources

**OIG Compliance Resource Materials**  
<https://oig.hhs.gov/compliance/compliance-guidance/compliance-resource-material.asp>

**RHC Conditions of Certification**  
<https://www.govinfo.gov/content/pkg/CFR-2017-title42-vol5/xml/CFR-2017-title42-vol5-part491.xml>

**CMS IOM Policy Benefit Manual, Chapter 13 (RHC)**  
<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c13.pdf>

**CMS IOM Claims Processing Manual, Chapter 9 (RHC)**  
<https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c09.pdf>

**SOM Appendix G**  
<https://www.cms.gov/files/document/appendix-g-state-operations-manual>

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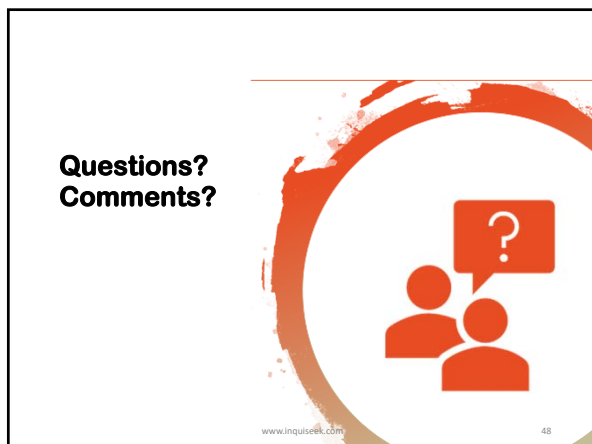
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**Patty Harper, RHIA, CHTS-PW, CHTS-IM, CHC®**  
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**318-243-2687**

Patty Harper is CEO of InQuiseek, LLC, a business and healthcare consulting company based in Louisiana. She has over 21 years of healthcare experience in the areas of healthcare finance & reimbursement, health information management, compliance, and practice management. She began her healthcare career as a hospital controller and reimbursement analyst. Patty holds a B.S. in Health Information Administration (cum laude) from Louisiana Tech University. She is credentialed through AHIMA as a RHIA, CHTS-IM, and CHTS-PW. Patty successfully completed AHIMA's ICD-10 Academy and has been recognized as an ICD-10 Trainer. She is also Certified in Healthcare Compliance (CHC®) through the Compliance Certification Board. Patty is a frequent speaker and contributor for national, state and regional and rural healthcare associations on these and other reimbursement-related topics. She has held memberships regional, state and national organizations throughout her healthcare career including NARHC, NRHA, AHIMA, MGMA, and HFMA. Patty currently serves on the Board of NARHC and LRHA.



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