A Compliance Professional's Tips and Techniques for Proposed, New and Updated Regulations and Guidance

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Gail Blacklock, Compliance Officer Astiva Health Jennifer Del Villar Director of Gov. Pro. Compliance Medicare Compliance Officer Cambia Health Solutions, Inc. Annie Hsu Shieh AVP, Compliance Molina Healthcare

Topics To Be Covered

 Techniques in reviewing and disseminating proposed, new, and updated regulations and guidance

 Collaboration with trusted compliance and internal colleagues book club anyone?

 How to implement regulatory change management and operationalize new requirements within the business

Monitoring & Auditing – Internally & Externally

Techniques in reviewing and disseminating proposed, new, and updated regulations and guidance

Regulatory Review - Federal Register



Federal Register:

- Each agency submitting a proposed or final rule document for publication shall prepare a preamble which will inform the reader, who is not an expert in the subject area, of the basis and purpose for the rule or proposal. The preamble shall and contain the following information:
- Important Information:
 - Issuing Agency
 - Action
 - Summary
 - Dates
 - Address
 - Contacts
- Supplementary Information
 The agency may include the following information in the preamble, as applicable:
 - A discussion of the background and major issues involved;
 - In the case of a final rule, any significant differences between it and the proposed rule;
 - A response to substantive public comments received; and
 - Any other information the agency considers appropriate.

Regulatory Review - Final Rule

READ THE COMMENTS & RESPONSES!



Communicate with regulators when guidance is unclear to obtain clarification & expectations

Note – when the proposed rule is available you have an opportunity to comment directly or through an industry trade group.

Regulatory Review - HPMS Memos and Manuals

Distribution

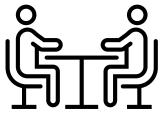
- Real-time distribution of CMS memos or manuals. (Within 24 hours if possible)
- Tracking the distribution.
- Point-out deadlines.
- How "hot" is the item. (What's the deadline, is an action required or more of an FYI.)
- Providing a high-level overview of the intent and requirements outlined.

Collaboration with trusted compliance and internal colleagues - book club anyone?

Trusted Partners



- Make sure you read the document and are versed in what it says.
- Read industry updates, FAQs and anything you can get your hand on from reputable sources
- Connect with trusted partners to collaborate!
 - Are their interpretations different than yours?
 - Why?
 - Discuss each item.
 - Look to industry collaborative efforts
 - Sign-up for CMS Part C & D Calls & Trainings
 - Attend industry-sponsored conferences that address upcoming regulations



How to implement regulatory change management and operationalize new requirements within the business

Regulatory Review - Sharing

Goal: Meet or Exceed the Expectations of Your Regulator

- Partnering with the business for successful compliance outcomes
 - Communication
 - Collaboration
 - Consultation

Regulatory Review - Sharing

Communication:

- High-Profile/Big-Ticket Regulatory Items
 - Add to monthly CMS-Issues Meeting Agenda if clarification is needed.
 - Track implementation
 - Review timelines (progress to goals)

Collaboration:

- Presentation during implementation to review milestones
 - Ensure the right CMS Regional Staff are present

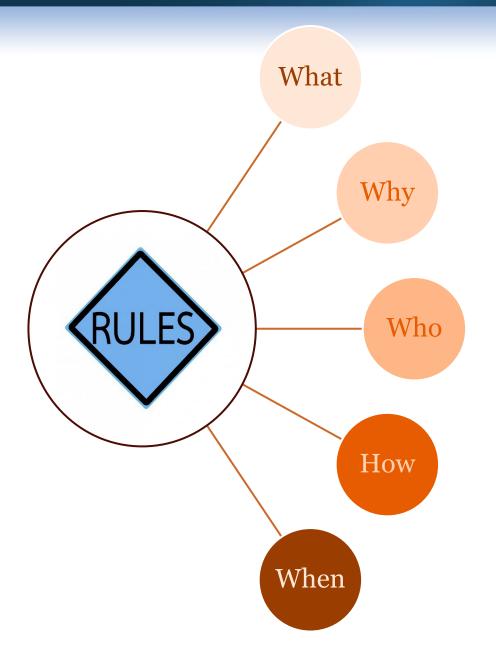
Consultation:

- Share ideas, ask for advice on implementation track
 - Follow-up with deliverables quickly

What's Required and/or Expected?

- Incorporate changes in applicable laws, regulations, and other program requirements to the following documents:
 - Standards of Conduct
 - Policies and procedures
 - General compliance training
- Must have an effective way to track, document, implement and communicate the new information:
 - Laws
 - Regulations & guidance for sponsors & FDRs
 - Statutory, regulatory, & sub-regulatory changes (e.g., HPMS memos)
 - Continuing education of understanding the regulator and the relationship (e.g who
 is your regulator and what are their goals, include compliance as part of your
 corporate onboarding of new staff)
- Include individuals from both your internal teams as well as your vendors.

Regulatory Review - Sharing and tracking



Create a document that captures:

What: What the rule is stating.

What are the risks.

What decisions were made.

Why: Background reason for the rule.

Insightful industry information.

Who: Who is executive owner.

Who are the stakeholders.

Who are the vendors.

How: Required tasks

When: Deadlines

Regulatory Implementation



Risk Assessment:

- Evaluate regulations and risks to the organization
 - Summarize potential risks (ex: compliance; resources; costs)
 - Educate leadership to ensure topdown approach and buy-in.

Work Plan

- Identified risks = add to Work Plan
 - Assign to Task Force/Team/Dept
 - Compliance collaboration
 - Ensure timely implementation and compliance with regulatory guidance
 - Tie Work Plan to compensation

How does the organization effectively monitor and audit the implementation of the regulation

What Needs to be Monitored (Internal/External)

Policies & Procedures

- Policy is regulatory requirement
- Tracking Implementation with steps help to create baseline for process
- Ensure policy creation includes responsible parties
- Include Monitoring & Auditing requirements
- Include process flow chart
- Review and update at least annually

Monitoring

- Create KPIs/Metrics that can quantitatively/qualitatively measure process
- Utilize any CMS or government provided benchmarks to measure
- Frequency of monitoring to ensure oversight
- Reporting/Monitoring by any delegated/contracted entities who share responsibility for the process

Auditing

- Scope & Methodology for Audit (CMS guidance/Accredited Agencies/etc)
- Audit Tools & Data Collection Lists # of FDRs audited/frequency
- Reporting of Audit Results (Internal/External Governing Body, CMS, etc)

Questions?

Contact:

Gail Blacklock, Compliance Officer

Astiva Health

Email: Gail.Blacklock@astivahealth.com

Jennifer Del Villar, Director of Government Programs Compliance, MCO Cambia Health Solutions, Inc.

Email: Jennifer.Delvillar@cambiahealth.com

Annie Hsu Shieh, AVP, Compliance

Molina Healthcare

Email: annie.shieh@molinahealthcare.com

THANK YOU