CONSULTING

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New URAC Regulatory Compliance

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New URAC Regulatory Compliance Requirements

The more things change, well the more things change. But one thing that doesn't change is that in an ever more demanding industry the demands continue to grow. See the recent announcement by URAC (attached) which outlines new requirements effective 5/15/21 regarding compliance to Regulatory requirements.

Specifically, the language states: 'The organization maintains compliance with applicable laws, regulations and requirements from any relevant jurisdictions. As a requirement of this Standard, organizations must remain in good standing with any issuing body/agency for all permits, licenses, registrations and/or charters held by the organization. If at any time during the accreditation or certification cycle this Standard is identified as "Not Met," the finding(s) will be presented to the Accreditation Committee for review and final determination of status.'

You might be thinking, what are the relevant jurisdictions? Herein lies the challenge, there are a lot of potential jurisdictions pertaining to pharmacy. A few months ago, D2 introduced an automated Regulatory Compliance Tool. The regulatory bodies tracked within this tool currently include:

- SBOPs (State Boards of Pharmacy)
- FDA (Food & Drug Administration)
- CMS (Centers for Medicare & Medicaid Services)
- DEA (Drug Enforcement Agency)
- NIH (National Institutes of Health)
- CFR (Code of Federal Regulations)
- CDC (Centers for Disease Control)
- DOT (Department of Transportation)
- EPA (Environmental Protection Agency)
- OIG (Office of Inspector General)
- HHS (Health & Human Services
- ISMP (Institute for Safe Medication Practices)
- NABP (National Association of Boards of Pharmacy)
- OCR (Office for Civil Rights)
- OSHA (Occupational Safety and Health Administration)
- OSG (Office of the Surgeon General)
- USDA (U.S. Department of Agriculture)
- CVM (Center for Veterinary Medicine)

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New URAC Regulatory Compliance Requirements (cont.)

Whenever I look at business requirements, I start by asking myself 3 fundamental questions:

- What needs to be done – and how do I keep track of the necessary requirements?
- Who is responsible within my team – to track, to do and to report results?
- When is it due – how do I know and how do I ensure I meet any requisite timelines?

So how do you track all of this information and ensure that it is both actionable and timely? The truth is you don't, in fact no one does as it is impossible for a pharmacy to track all this information. There are simply not enough hours in the day, with all of the duties required within a pharmacy. Of course, we all read some updates and TRY to stay current, it just isn't truly feasible and therefore doesn't happen potentially leaving issues on the table that go unresolved. These unresolved issues may lead to compliance issues which can include fines in addition to challenges in getting into a payer network.

What is the resolution, in comes D2? As part of our Compliance Tool Set, D2 is currently providing our Regulatory tracking tool to numerous industry stakeholders. This includes the tracking of all the bodies referenced above. Our tool then helps to prioritize items for review, track items that need to be corrected and Alert Escalation to ensure items don't get lost.

It would be a privilege to provide you a demo of this industry leading technology and allow you to hit the Easy Button of Regulatory Compliance.

For more information, please contact
Quintin Jessee email quintin.jessee@d2rx.com or 614.753.1176

April 15, 2021

Sent via email

Re: New Regulatory Compliance Standard

Dear URAC Client,

As the nation's leading health care accreditor, URAC values patient care and safety first. When we discover an improvement opportunity that could enhance patient safety within our standards, we work quickly to incorporate the additional knowledge into our programs.

Therefore, URAC is introducing a new regulatory compliance Standard. Effective May 15, 2021, this new Standard will apply to all current, non-deemed applications, accreditations and certifications. Although we expect immediate compliance with this Standard, we will not be asking for any additional documentation from our clients at this time. As new versions of programs are released, this Standard will be built into the program requirements and documentation will be submitted on Desktop.

Attached you will find the Standard language (see Attachment A). As a requirement of this Standard, organizations must remain in good standing with any issuing body/agency for all permits, licenses, registrations and/or charters held by the organization. If at any time during the accreditation or certification cycle this Standard is identified as "Not Met," the finding(s) will be presented to the Accreditation Committee for review and final determination of status.

If you have any further questions, please reach out to Client Relations at clientrelations@urac.org. In addition, you can reach out to the Product Development Department at productdevelopment@urac.org.

Sincerely,
Jenn Richards, PharmD, JD, CSP
Product Development Principal
Email: productdevelopment@urac.org

Attachment A: URAC's New Regulatory Compliance Standard

Standard: Regulatory Compliance

The organization maintains compliance with applicable jurisdictional laws and regulations.

Regulatory Compliance

The organization:

a. Maintains compliance with applicable laws, regulations and requirements from any relevant jurisdictions