1. What is the problem?
2. Is the problem about patient or public risk?
   - No - Stop, don't regulate. If the problem is not about risk there's no need to regulate.
   - Yes - go to 3

3. What are the risks?
4. How great are the risks?
5. Are the risks currently managed? (by whom/how/evidence)
   - Yes - Stop, don't regulate, use the existing solution to manage the problem
   - No - go to 6

6. Where and why is the problem occurring?
7. Can the problem be solved locally? (employer, consumer, government)
   - Yes - Stop, don't regulate, use targeted local approaches
   - No - go to 8

8. Is there a regulatory solution in line with the principles of good regulation?
   - No - consider other regulatory options – go back to 6
   - Yes - go to 9

9. Are there any new risks or unintended consequences?
   - Yes - Stop, consider other regulatory options – go back to 6
   - No - regulate, Review regularly and respond to change

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Adapted from Council on Healthcare Regulatory Excellence (CHRE)