Chapter 11-850, Medical Cannabis Dispensaries – Summary of major changes

1) Changes to conform with numerous changes to chapter 329D, HRS, since 2015
2) Edible cannabis products
   a) Statutory definition applies to several existing product types (capsules, lozenges, pills, oils, tinctures)
   b) List of new allowed product types: gummies, hard molded confections made primarily from sugar or syrup, chocolates, cookies, brownies, honey, beverages, powdered beverage mixes or beverage additives, syrup beverage mixes or beverage additives
   c) Safety measures
      i) Cannot require time/temperature control for safety (determination involves water activity, water activity and pH, or product assessment)
      ii) Homogenous in cannabinoid content
      iii) Labeling
         (1) Serving size
         (2) Per serving mg of total THC, CBD, and "any other cannabinoid specifically listed or described in the label or packaging"
         (3) Allergen statement
      iv) Packaging with portioning guide
      v) New language to restrict 'appeal to minors':
         (1) Not designed to resemble commercially available candy or other products marketed to children
         (2) Not in the shape of or contain a depiction of a human, animal, or fruit
         (3) "Candy" and "candies" not used on packaging, labeling, advertising
      vi) No infused oils and butters containing garlic and peppers (high botulism risk)
      vii) Tinctures: 2 oz maximum, labeled for intended use in drops or dropperfuls
3) Additional safety measures for all products
   a) No added ingredients in cannabis
   b) Banned components/ingredients in manufactured cannabis products
      i) FDA food/cosmetics banned components/ingredients
      ii) Psychoactive ingredients not derived from cannabis
      iii) Ingredients that "increase the potency, toxicity, or addictive potential of the product or create a potentially unsafe combination with cannabinoids"
      iv) Cannabinoids created through isomerization
      v) Synthetic cannabinoids
   c) Solvents and processing
      i) Require food-grade solvents
      ii) Ban US Pharmacopeia class 1 solvents ("unacceptable toxicities or deleterious environmental effects")
      iii) Ban open butane processing (consistent with §328G-3(d) regarding hemp processing) and "any other method of processing the department determines poses a risk to health and safety"
   d) Good Manufacturing Practices and Quality Control; effective immediately for new products, effective Jan 1, 2023 for all products
   e) Labeling and dosage limits

i) Changed limits from delta-9-THC to total THC (10 mg/serving and 1000 mg/package; total THC = D9-THCA*0.877 + D9-THC + D8-THC + D10-THC)
ii) Label concentration for total THC and “any other cannabinoid specifically listed or described in the label or packaging”
iii) Ingredient statement
iv) Labeling for products intended for topical use: “For external use only”

f) Explicit ban on sale to minor qualifying patients/qualifying out-of-state patients
g) Adverse event reporting
h) Reserve samples

4) Sampling
   a) Definitions relating to sampling (batch, final form, representative sample)
   b) Sample representativeness, timing, size
   c) Sampling plan and recordkeeping
5) Testing
   a) Testing for “any other cannabinoid specifically listed or described in the label or packaging”
   b) Revised solvents list; include banned solvents
   c) List of pesticides (currently in policy, not in rules)
   d) Revised microbial contaminants list; allow non-plating methods
   e) Change from moisture content to water activity (for cannabis)
6) Separate hemp production and processing from medical cannabis and manufactured cannabis product production
   a) No hemp allowed in medical cannabis production centers
   b) Chapter 11-37 compliant hemp ingredients may be used as an ingredient in a manufactured cannabis product