Good afternoon, All
Please see below for comments. Thank you for the opportunity to participate.

- **836-200-0505(11) "Reporting Manufacturer" Definition**
  - The definition for a reporting manufacturer requires that all of the listed criteria must be met, however, a virtual manufacturer does not seem to meet the criterion outlined in (b) as they do not engage in the manufacture of prescription drugs in accordance with the definition provided under ORS 646A.689(1)(d): "*Manufacture*" means:
    - *(i) The production, preparation, propagation, compounding, conversion or processing of a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; and*
    - *(ii) The packaging or repackaging of a drug or labeling or relabeling of a drug container.*
  - Are virtual manufacturers intended to be included? It would appear that way due to the language in (c). It seems as though this definition needs more clarity on virtual manufacturers and whether or not they qualify as reporting manufacturers.
  - Note: A **virtual drug manufacturer** is a person or entity that sells prescription drugs, devices, or products but doesn't physically possess them (therefore, they could not be involved in any of the activities listed in *(i)* and *(ii)* above). Instead, they outsource the manufacturing and distribution to a third party, such as a contract manufacturing organization (CMO). Virtual drug manufacturers can use technology and collaboration to streamline the drug development process and bring new treatments to market faster. However, they must ensure that incidents or potential incidents are reported to the manufacturer that holds the rights to the product design.
- **836-200-0531(1)(d)(A)**
  - "*Other prescription drugs, regardless of generic or brand status, including the availability, price, drug name, and labeler name*" - A manufacturer cannot speak to the availability of a different manufacturer's product. It is also questionable if manufacturers should be providing information on the products of another manufacturer, and if they would, it may require disclaimers because they do not have all insights into product information for other manufacturers. Also, what if a manufacturer in good faith accidentally provided incorrect information on another manufacturer's product and it were publicly posted (e.g., lawsuits, etc.).
- **836-200-0531(1)(d)(G)**
  - "*Other costs not specifically associated with the prescription drug.*" - More clarity could be provided concerning this. What other costs are anticipated to be included under this category?
- **836-200-0540(1)(b)**
  - "*Each filing that contains information claimed as trade secret by the manufacturer must include, and for each individual piece of information claimed as trade secret, the name of the data element and a detailed written explanation, and factual information demonstrating why the information is exempt from under all of the following requirements:*" - The manufacturer is providing information demonstrating the following requirements (e.g., not patented, known only to certain individuals, etc.). They are not providing information demonstrating why the information is "exempt from under all the following requirements." This sentence is confusing and perhaps requires a bit of rewriting for clarity.

Have a great week,
Lynetta

Lynetta Moore (she/her)
Director, BPaaS