Sections 5081 through 5088 of the 21st Century Cures discussion draft would establish the Device Distribution Licensing Act of 2015 (the Act). The attached table summarizes the Act’s requirements.

- The Act establishes uniform national standards for licensing third-party logistics providers (3PLs) and wholesale distributors of prescription medical devices. Related state requirements will be preempted.
- Individual states will continue to license wholesale distributors and 3PLs, but must do so using the uniform national standards. A federal license will be available in states that choose not to license wholesale distributors and 3PLs.
- The Act does not affect federal licensing requirements for manufacturers or state licensure requirements for dispensers.
- The Act does not affect medical device tracing. The Unique Device Identifier (UDI) system addresses traceability, and this Act does not add to or otherwise impact existing medical device identification or tracing requirements.

Rationale for Action

1. The revision and/or preemption of state licensure requirements for drug distribution pursuant to the Drug Supply Chain Security Act (DSCSA) has significant potential to create confusion as to the regulation of medical device distribution.

   Nearly every state that requires licensure for medical device distribution does so as part of its prescription drug licensure requirements. Because the DSCSA will require states to amend their drug licensure requirements—or preempt those requirements—over the next two years, there is significant regulatory uncertainty related to medical device distribution licensure. State-specific “fixes” to this uncertainty could lead to an even more complex patchwork of regulations than exists today.

2. The divergence of licensure standards used by States creates unnecessary burden.

   The standards for wholesale distribution of medical devices vary widely from state to state. Some states have no licensure requirements for medical device distributors, while others rely on only minimal requirements. Additionally, many states impose licensure requirements that do not have logical application to device distributors. The wide variation in regulatory standards for distribution among states can make compliance challenging for even the most well-intentioned and sophisticated distributors.

3. Uniform standards will help to further secure the device distribution chain.

   A safe, secure distribution chain requires a mechanism to deter illegitimate devices from entering the distribution chain through unlicensed entities as well as a mechanism for identifying and removing those illegitimate products that manage to infiltrate the distribution chain. This two-prong approach was clearly adopted for pharmaceutical products through the DSCSA. With regard to medical devices, the FDA has already established an effective method for identifying and removing illegitimate products through development of the UDI system, and industry has begun implementation of those systems and processes. Uniform national licensing standards for distribution of medical devices would provide the important second prong of a system to secure the distribution chain.

4. Uniform and predictable regulation of the interstate distribution of medical devices promotes principles of good governance.

   Uniform, predictable regulation would support the efficient movement of medical devices—many of which are life supporting or life sustaining—in interstate commerce. Such regulation would also promote fair competition and economic efficiencies in distribution. All of these things would reduce health care costs, improve patient choice, and support the rapid delivery of necessary medical devices.
## SECTOR BY SECTOR REQUIREMENTS

<table>
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<th>Sector</th>
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| Manufacturers           | • Must work only with trading partners that are authorized (*i.e.*, properly licensed)  
                          | • No state or federal wholesale distribution or 3PL licensure requirements apply when distributing own devices  
                          | • Subject to licensure as a wholesale distributor only when distributing Rx devices other than own devices (see wholesale distributor requirements below) |
| Wholesale Distributors  | • Must work only with trading partners that are authorized (*i.e.*, properly licensed)  
                          | • Must be licensed to distribute prescription devices to or from a state  
                          | • States will license wholesale distributors using uniform national standards  
                          | • Federal license available in states choosing not to license wholesale distributors  
                          | • Separate device license not required if licensed to distribute drugs under Drug Supply Chain Security Act (DSCSA)  
                          | • Licensure required only with regard to prescription medical devices, as defined by Federal Food, Drug, and Cosmetic Act  
                          | • Intracompany transfers are not wholesale distribution activities for which licensure is required |
| Third-Party Logistics Providers | • Must work only with trading partners that are authorized (*i.e.*, properly licensed)  
                                | • Must be licensed to engage in 3PL activities in a state  
                                | • States will license 3PLs using uniform national standards  
                                | • Federal license available in states choosing not to license 3PLs  
                                | • Separate device license not required if licensed as a drug 3PL under the DSCSA  
                                | • Licensure required only with regard to prescription medical devices, as defined by Federal Food, Drug, and Cosmetic Act  
                                | • Must not be regulated as wholesale distributors (unless actually engaged in wholesale distribution) |
| Dispensers              | • Must work only with trading partners that are authorized (*i.e.*, properly licensed)  
                          | • No state or federal wholesale distribution or 3PL licensure requirements apply when purchasing devices for dispensing or transferring devices intracompany  
                          | • Subject to licensure as a wholesale distributor only when purchasing devices for resale to a third party other than the end user |
DEVICE DISTRIBUTION UNIFORM STANDARDS ALLIANCE

About Us

The Device Distribution Uniform Standards Alliance (DDUSA) is a coalition of national and regional medical device supply chain stakeholders established to promote uniformity and predictability in state regulation of medical device distribution. DDUSA seeks to establish consistent regulation of medical device distribution among the states and between state and federal agencies.

Membership

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