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## Regulatory Changes to Stat-Drug Boxes

The Virginia Board of Pharmacy has recently recommended fast-track regulations that will address the current inadequacies associated with the use of stat-drug boxes in nursing and assisted living facilities. Stat-drug boxes are prepared by a pharmacy to allow for the initiation of therapy prior to the receipt of ordered drugs from the pharmacy and are used under the condition that there is an order by a prescriber for any drug removed from the stat-drug box. Currently, the stat-drug boxes are limited to containing Schedule III through V drugs only. If ultimately approved, the fast-track regulations promise to aide long term care providers in timely providing appropriate pain management care – which often includes Schedule II controlled substances – to residents.

### Current Regulations

Under the current regulations, “[t]he stat-drug box shall contain no Schedule II drugs,”<sup>1</sup> and is therefore limited to Schedule III through V drugs. Furthermore, under the present regulations, the stat-drug box can contain only one Schedule III through V drug from each therapeutic class, with no more than five (5) doses of each. Much to long term care providers’ dismay, the current regulations preclude the inclusion of

many important Schedule II pain management medications.

Several months ago, long term care providers, represented by the Virginia Health Care Association, requested that the Virginia Board of Pharmacy consider changing its regulations to allow Schedule II controlled substances to be regularly maintained in stat-drug boxes. Providers stressed that the inclusion of Schedule II drugs is critical in allowing for the prompt initiation of certain pain medications upon admission into a long term care facility. The interested parties further explained that both resident admissions and orders for medications can – and often do – occur on nights and weekends, when it is impossible to obtain medications from pharmacies in a timely manner. Even under the best circumstances (i.e., when an admission or an order comes in midweek and early enough during the day), there is typically at least a six to eight hour delay in receiving ordered medications from a pharmacy. While it is generally understood that a prompt first response will lead to more effective pain management and better outcomes for residents, long term care providers who fail to timely initiate certain Schedule II drugs as

<sup>1</sup> 18 VAC 110-20-550 (5)(b).



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ordered may be in danger of violating Centers for Medicare and Medicaid Services (CMS) and Virginia Department of Health (VDH) standards as well.

After assessing the financial and logistical feasibility of several other options, including the possibility of obtaining discharge medications when residents are sent from the hospital to the nursing home as well as the use of automated dispensing devices (ADD), the Board of Pharmacy ultimately agreed with providers that such alternative options were not viable. In June 2009, the Board appointed an internal committee to develop a recommendation with respect to the appropriate contents of the stat-drug box.

#### Newly Recommended Fast-Track Regulations

In response to providers' concerns as enumerated above, the Board Committee ultimately proposed fast-track regulations that will allow Schedule II drugs to be included in stat-drug boxes, in addition to Schedule III through V drugs. Notably, the Board opted to pursue the fast-track regulatory process, which is reserved for regulatory changes that are considered to be non-controversial, and to which little or no opposition is expected.

Under the new regulatory regime, up to twenty (20) solid dosage units of Schedule II drugs may be included in the stat-drug box. Similarly, up to 20 solid dosage units of Schedule III, IV, and/or V drugs, may be included in the stat-drug box as well. The amended regulations also provide for an equivalency conversion between liquids and solids. Specifically, the proposed fast-track regulations state:

"The stat-drug box shall contain no more than twenty (20) solid dosage units per schedule of

Schedule II through V drugs except that one unit of a liquid, not to exceed 30 ml, may be substituted for a solid dosage unit. If the unit of a liquid, that may contain more than one dose, is removed from the stat box pursuant to a patient order, then the remainder shall be stored with that patient's other drugs, may be used for subsequent doses administered to that patient, and shall not be administered to any other patient."

At a September 2, 2009 meeting of the full Board of Pharmacy, the Board adopted the aforementioned fast-track regulations and subsequently sent them to the executive branch for review. After executive branch approval, the regulations will be published in the *Virginia Register* and a 30-day comment period will commence. Barring any objections by a member of the applicable standing committee of the Senate or House of Delegates, and barring objections by 10 or more members of the public, the regulations will become effective 15 days after the close of the comment period. (In the event that objections are received by the appropriate parties above, the publication of the fast-track regulation will instead serve as a Notice of Intended Regulatory Action and the standard rulemaking process will be followed to promulgate the regulation.)

Should you have any questions about the proposed regulatory changes to stat-drug boxes, or for more information, please contact Mary Malone, Jeannie Adams or Emily Towey at 804.967.9604 or by e-mail at [mmalone@hdjn.com](mailto:mmalone@hdjn.com), [jadams@hdjn.com](mailto:jadams@hdjn.com), or [etowey@hdjn.com](mailto:etowey@hdjn.com). Additional information about Hancock, Daniel, Johnson & Nagle, P.C. is available at the firm's website at [www.hdjn.com](http://www.hdjn.com).



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