



November 30, 2015

Pharmaceutical Working Group  
c/o Angelo J. Bellomo, REHS, QEP  
Deputy Director for Health Protection  
5050 Commerce Drive  
Baldwin Park, CA 91706

*Sent via Email to: [EPR@lacounty.gov](mailto:EPR@lacounty.gov)*

**RE: Opposition to the Proposed Draft Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance**

Dear Mr. Bellomo:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), I am writing to oppose the proposed draft Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance.

AdvaMed is the primary national trade association representing manufacturers of medical devices, diagnostics, and health information systems. Our members produce the life-saving and life-enhancing products that are improving healthcare outcomes while reducing overall costs. In California, the medical technology industry contributes over \$58.9 billion to the state economy and is responsible for 84,000 direct and indirect jobs in the state. Included within AdvaMed's membership are the leading manufacturers of needles and syringes as well as products designed to ensure the safe containment and disposal of medical sharps.

Advances in medical care have enabled many people to manage their medical conditions in their homes. Although there are multiple options in place for sharps disposal, the increase of home users has led state and local governments to move to ensure that sharps are disposed of appropriately. In fact, discussions are currently ongoing in the California state legislature with a focus on a state-wide approach to the disposal of household hazardous waste, including sharps. In that vein, AdvaMed is part of a group of associations that has committed to helping establish an entity dedicated to providing education to California consumers about the appropriate handling and disposal of our industries' products. Los Angeles County may wish to consider allowing that debate, which could preempt local government on this topic, to take place before taking action on the draft proposed ordinance.

Because numerous entities are involved in the generation of medical sharps waste, including consumers, manufacturers, retailers and healthcare providers, AdvaMed believes that NO one group should bear full responsibility for containment and disposal. Unfortunately, the

proposed ordinance puts the full burden of sharps disposal on sharps manufacturers. Placing the entire burden of waste on the manufacturers ignores the complexity of medical device distribution and supply chain mechanics, and attempts to regulate this matter without any significant input from and participation by other crucial stakeholders, including the end user.

Additionally, the ordinance is unnecessary, unprecedented and the first of its kind to call for a mandatory industry-funded sharps take back program. No other municipality has included sharps in their stewardship ordinances in part because they are inherently different from pharmaceuticals and are required to be disposed of uniquely due to California law. California Health and Safety (H&S) Code Section 118286 prohibits individuals from discarding home-generated sharps waste in the home or business recycling or waste containers. We question the rationale behind including both product categories in a single ordinance and strongly urge that sharps be exempted.

Furthermore, there is no need to create an entirely new system or program when a range of current options are already in place to minimize cost and increase convenience to the consumer. Currently there are numerous public and private sector sharps disposal solutions already available to consumers. In fact, DPW staff expressed concern to our industry directly that current collection sites are “overwhelmed.” This heightened concern would leave us to believe our existing industry education efforts are working well and patients are complying with the law. Other successful examples of existing industry funded and other education efforts and resources include:

- Patient education by health care providers on how to properly dispose of used sharps.
- Materials on safe disposal are also available in packaging inserts that come with their medicines. Some manufacturers currently offer call center and website support and training on using and disposing of sharps.
- The use of pre-filled pens, needles with a safety sheath and availability of existing manufacturer mail back programs for those consumers seeking a more convenient method of disposal should be recognized as a proactive step in patient safety.
- A listing of 616 sites on [www.calrecycle.ca.gov](http://www.calrecycle.ca.gov) to dispose of used sharps. Many jurisdictions also offer ‘at your door’ or curbside pickup for sharps as well. LA County and its Cities have successful sharps disposal programs in place that include biopharmaceutical and sharps manufacturers.
- Over 100 home-generated sharps consolidation points spread across the County, from Calabasas to Downey, Inglewood, Compton, Los Angeles, Northridge, San Pedro, West Covina, and many others throughout the County.

Other concerns with the draft proposed ordinance include:

- The abdication of the County’s public duty to consider the benefits and the costs of this policy proposal. Requires that all of the costs be paid by private entities while providing neither demonstration of benefit nor a mechanism to gauge the efficacy of the program once in place.



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Advanced Medical Technology Association

- An exemption for retailers from participating in the takeback program. At a minimum, participation by retail pharmacies should be mandatory, as that is where the patient interface takes place. Retailer involvement is a key component in EPR programs in Canada and Europe
- Syringes found on beaches and parks and other collateral damage resulting from illegal drug and needle use would not be addressed by this ordinance and will not be remedied. Current needle exchange programs and existing state law for pharmacies selling syringes encourage safe disposal within this segment of the population. No data or studies have been presented that document where improper sharps disposal originates.
- The ordinance permits incentives to encourage participation in the program by retail pharmacies. This concept violates federal anti-trust law and anti-kickback statutes.
- The creation of a private right of action. This action lacks precedent and appears to be an attempt to involve non-profits and for profit entities who benefit financially from passage of the ordinance.
- As the majority of sharps are sold to public payers under the MediCare and MediCal programs, it is impossible for our companies to recuperate the costs of the program mandated here, as those federal programs do not allow for reimbursement of costs related to takeback programs.
- The exemption of medical devices in the definition of “covered drug”. Sharps are considered a medical device.

In summary, we believe that sharps should be excluded from the ordinance. Should the County Board choose not to exempt sharps from the ordinance altogether, it should consider allowing the related debate in the state legislature to take place before acting. Existing sharps take back programs are already operating successfully in LA County. Layering in new costly programs will only lead to patient confusion, create a patchwork of inconsistent regulations, and deter innovation and improvement of sharps disposal technologies.

For all the reasons stated above, we strongly oppose the Los Angeles County Pharmaceuticals and Sharps Collection and Disposal Stewardship Ordinance. Please feel free to contact me with any questions or concerns.

Sincerely,

Carrie A. Hartgen  
Vice President, State Government & Regional Affairs

cc: Members, Los Angeles County Board of Supervisors