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November 24, 2015

Pharmaceutical Working Group

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

RE: Los Angeles County EPR Pharmaceuticals and Sharps Ordinance

Dear Mr. Bellomo,

The Hospital Association of Southern California (HASC) represents over 85 hospitals in Los Angeles County. HASC appreciates the opportunity to provide comment on the Extended Producer Responsibility (EPR) Pharmaceutical Take Back draft ordinance that would enable the County of Los Angeles to address issues of pharmaceuticals and sharps disposal by end-users. While hospitals support the overarching goals and objectives of the program, they do so within the confines of existing regulations mandated by a myriad of federal, state and local regulatory agencies for disposal of pharmaceuticals and sharps, which include the United States Environmental Protection Agency (EPA), Drug Enforcement Agency (DEA), Centers for Medicare and Medicaid Services (CMS), California Board of Pharmacy, and the California Department of Public Health (CDPH).

Hospitals are committed to the health and safety of its patients, staff, and the communities that they serve. Patients are counseled on the proper use of medications, and this education also extends to the seventy-four Emergency Departments who voluntarily adopted the Safe Pain Prescribing Guidelines to reduce the upward trajectory of opiate abuse.

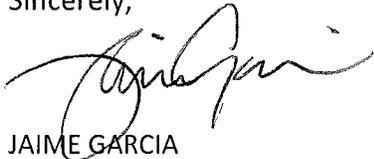
The EPR ordinance is designed to establish for the end-user a program for the disposal of pharmaceuticals and sharps that might otherwise end up in the wrong hands or put sanitation workers at-risk. As written, the draft ordinance is unique in the respect that it includes sharps, which is regulated differently than pharmaceuticals. It is therefore important to have a clear understanding of the ordinance in terms of the regulatory framework hospitals operate under and unintended consequences of designating them as a collection site. Foremost, hospitals are required on a federal level by USEPA and USDEA, and on a state level by the Department of Public Health to separately identify and manage Hazardous Pharmaceuticals, Non-hazardous Pharmaceuticals, Controlled Substances, and sharps. Proper segregation is mandated as security and proper disposal requirements differ by the type of waste. Packaging and labeling requirements are specific to the type of waste, and disposal destinations are different for each.

If a hospital does not properly comply with these federal and state requirements they are subject to fines, other penalties, and possible loss of their license. These fines can be up to \$5000.00 per violation per day, and the aspect of having a license suspended or revoked has drastic public health consequences.

While a single collection container that is accessible by the public may work well at other locations, the inclusion of hospitals would put the hospital at risk of being non-compliant and liable. The DEA and Board of Pharmacy in particular have very specific requirements for both security and packaging of waste, which include controlled substances, under their jurisdiction. These requirements are in place to keep illicit drugs off the street and deviation from those requirements is strictly prohibited.

I thank you in advance for your time and please feel free to contact me (213)538-0702 with any questions as the County works to further refine the draft ordinance.

Sincerely,



JAIME GARCIA

Regional Vice President – Los Angeles Region