ECLEG JUL10'17 AM10:47

LOCAL LAW TO BE ENACTED BY
THE ERIE COUNTY LEGISLATURE
IN THE
COUNTY OF ERIE

LOCAL LAW INTRO. – NO. 12-1 - 2017

LOCAL LAW – NO. _____ - 2017

A LOCAL LAW requiring disclosure of origin and composition of all manufactured parts in surgically implanted dental devices.

SECTION 1. Legislative Findings
This honorable body hereby finds and determines that many dental implants and devices are not adequately regulated by any of the federal government's quality control agencies, like the Food and Drug Administration (FDA). This body further finds and determines that a better informed consumer is able to make better choices for his or her health and well-being. To that end, this law is enacted to require all manufacturers and retailers of surgically implanted dental devices operating in Erie County to disclose the country of origin with regard to raw materials and manufacturing prior to any sale.

SECTION 2. Definitions
1) Covered Commodity – A covered commodity is any dental device, material, or prostheses that is surgically implanted and/or inserted into the end consumer's mouth.
2) Country of Origin
    a. United States County of Origin – A retailer of a covered commodity may designate the covered commodity as exclusively having a United States country of origin if:
        i. The covered commodity was manufactured and assembled from parts manufactured and assembled exclusively in the United States.
    b. Foreign Country of Origin or Multiple Countries of Origin – If any component or raw material of a covered commodity is manufactured or assembled in any country other than the United States, a retailer of said commodity must list all counties that took part in the covered commodity's manufacture and assembly.
3) Manufacturer – A manufacturer for the purpose of this law is any company that assembles, prints, or finishes a covered commodity for sale to any Retailer in Erie County.
4) Retailer – A retailer for the purpose of this law is any medical device supplier, including, but not limited to dentists, oral surgeons, or DMDs who will surgically insert or affix any covered commodity into a consumer's mouth for the consumer's personal use.
5) Consumer – A consumer for the purposes of this law is the end user of a covered commodity.

SECTION 3. Requirement for Disclosure

1) A manufacturer of a covered commodity shall, at the time of sale to a retailer, disclose the country of origin of any and all raw materials used in the covered commodity as well as the country of origin of final assembly and component parts.
    a. Said disclosure shall be in writing and signed by both the manufacturer and retailer at the time of sale. A sample form is attached hereto in Appendix A.
2) A retailer of a covered commodity shall, at the final point of sale, disclose to consumers the country of origin of any and all raw materials used in the covered commodity as well as the country of origin of final assembly and component parts contained in the covered commodity.
    a. Said disclosure shall be in writing and signed by both the retailer and consumer prior to the date of the implant procedure. A sample form is attached hereto in Appendix A.

SECTION 4. Penalties

A party is in violation of this law if a covered manufacturer or retailer fails to provide the necessary disclosure as described in the previous section.

Any party found in violation of this law shall be fined no more than $1,000 for the first incident, $2,500 for the second incident, and $5,000 for each incident thereafter and subject to a Class A Misdemeanor.

SECTION 5. Effective Date

This Local Law shall take effect upon 60 days from its filing with the Secretary of State.

SECTION 6. Severability.

If any clause, sentence, paragraph, subdivision, section or part of this Local Law or the application thereof, to any person, individual, corporation, firm, partnership, entity or circumstance, shall be adjudged by any court of competent jurisdiction to be invalid or unconstitutional such order of judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, subdivision, section or part of this Local Law or in its application to the person, individual, corporation, firm, partnership, entity, or circumstance directly involved in the controversy in which such judgment or order shall be rendered.

Sponsor: Legislator Joseph C. Lorigo

Appendix A. Medical Device Disclosure Form

1) Medical Device:_____

2) Location of Implant:_____

3) Country of origin, if item is manufactured from components or raw materials with origin different than that listed in 3(a) also fill out 3(b):

   a. County of origin:_____

   b. Country of origin for component materials used in assembly:

      i. _____

      ii. _____

      iii. _____

      iv. _____ (if additional space is needed attach additional pages)

I, _____, the undersigned have provided my patient,_____, with the above information regarding the national origin of all medical devices associated with their procedure _____.

_____ _____

Medical services provider signature Date

_____ _____

Patient signature confirming receipt Date