

BILL ANALYSIS

SENATE COMMITTEE ON HEALTH
 Senator Ed Hernandez, O.D., Chair

BILL NO: AB 1867
 AUTHOR: Pan
 AMENDED: March 29, 2012
 HEARING DATE: June 6, 2012
 CONSULTANT: Marchand

SUBJECT : Health facilities: equipment standards.

SUMMARY : Extends, until January 1, 2016, the implementation date of a prohibition on the use of an epidural, intravenous, or enteral feeding connector that fits into a connection port other than the type for which it was intended. Under current law, for intravenous and enteral feeding connectors, this prohibition is scheduled to take effect on January 1, 2013, while the prohibition on these types of epidural connectors is scheduled to take effect on January 1, 2014.

Existing law:

1. Provides for the licensing and regulation of health facilities, including general acute care hospitals, acute psychiatric hospitals, and special hospitals by the Department of Public Health (DPH).
2. Requires general acute care, acute psychiatric, and special hospitals to develop, implement, and comply with a patient safety plan for the purposes of reducing preventable patient safety events. Includes, among the patient safety events that must be included in a hospital's patient safety plan, patient deaths or serious disabilities that are associated with the use of a device, including but not limited to a catheter, drain, or other specialized tube, infusion pump, or ventilator, in which the device is used or functions other than as intended.
3. Prohibits, beginning 36 months after the publication of a new design standard for connections for epidural applications by the International Organization for Standardization (ISO), or January 1, 2014, whichever occurs first, general acute care, acute psychiatric, and special hospitals from using an epidural connection that would fit into a connection port other than the type it was intended for, unless an emergency or urgent situation exists and the prohibition impairs the ability to provide health care.

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4. Prohibits, beginning 24 months after the publication of a new design standard for connections for intravenous or enteral applications by the ISO, or January 1, 2013, whichever occurs first, general acute care, acute psychiatric, and special hospitals from using an intravenous or enteral feeding connection that would fit into a connection port other than the type for which it was intended, unless an emergency or urgent situation exists and the prohibition would impair the ability to provide health care.
5. Requires the Advanced Medical Technology Association, on January 1 of each year until the standards are developed, to provide the Legislature with a report on the progress of the ISO in developing new design standards for connections for intravenous, epidural, or enteral applications.
6. Requires a health facility that is required to develop a patient safety plan, as specified, to include in the patient safety plan measures to prevent adverse events associated with misconnecting intravenous, enteral feeding, and epidural lines. Requires this provision to become inoperative when the above provisions take effect prohibiting the use of connections that can fit into connections other than those intended.

This bill:

1. Extends the implementation date of a prohibition on the use of an epidural connection that fits into a connection port other than the type for which it was intended, from January 1, 2014, or 36 months after the publication of a new design standard, whichever occurs first, and instead prohibits the use of these epidural connections beginning on January 1, 2016.
2. Extends the implementation date of a prohibition on the use of an intravenous connection or an enteral feeding connection that would fit into a connection port other than the type for which it was intended, from January 1, 2013, or 24 months after the publication of a new design standard, whichever occurs first, and instead prohibits the use of these intravenous or enteral connections beginning on January 1, 2016.

FISCAL EFFECT : According to the Assembly Appropriations Committee, this bill has negligible state fiscal impact.

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PRIOR VOTES :
 Assembly Health: 17- 0
 Assembly Appropriations:17- 0
 Assembly Floor: 74- 0

COMMENTS :

1.Author's statement. According to the author, SB 158 (Florez), Chapter 294, Statutes of 2008, became law as a multi-pronged bill that addressed a number of issues designed to improve patient safety and decrease infections in a variety of health care environments. Included in SB 158 was a requirement that, as of January1, 2011, all hospitals must use separate unique connectors for intravenous, enteral (feeding tube) and epidural connections. The intent was to address past mistakes in hospital environments where an employee switched one type of line with another, causing serious injury or death.

The author states that hospitals and other health care facilities depend on a variety of catheters, tubing and syringes to deliver medications and other substances to patients through vascular, enteral, respiratory and epidural delivery systems. The delivery systems listed above (vascular, enteral, etc.) frequently employ fittings called Luer connectors to link various system components. The male and female components of Luer connectors join together to create secure yet detachable leak-proof connections. Multiple connections between medical devices and tubing are common in patient care. Thousands of these connections are used in hospital environments in California daily, with millions sold annually. These products are critical to the daily care of patients in all parts of a hospital environment. The process of creating a unique connector that can be adopted by all manufacturers and interchangeable among pumps for that specific medication can take over two years to develop the design alone.

According to the author, the Food and Drug Administration (FDA) has been actively participating in an international effort with the ISO to develop and implement standards for non-interchangeable connectors for small-bore medical connectors used in intravascular, breathing systems, enteral, urethral/urinary, cuff inflation, and neuraxial applications. Once implemented, these connectors will facilitate correct connections and eliminate incompatible tubing misconnections.

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The author states that unless there is an industry standard for connections, hospitals will have to purchase proprietary products and accessories at incredible cost. Additionally, each hospital may have different equipment for one of the most common functions in medical care. This could create confusion and possibly risk patient safety.

According to the author, there is no way to develop international standards in time to meet the deadlines in California law, and therefore, a delay is critically needed. Extending the deadline will allow the ISO to complete its work and allow the industry to meet this important mandate through a common design format.

The goal of this proposal is to promote patient safety through the creation of publicly available designs for each unique connection, but to do it thoughtfully and correctly.

2.Adverse events related to misconnections of devices and lines.

According to the FDA, hospitals and other health care facilities depend on a variety of catheters, tubing and syringes to deliver medications and other substances to patients through vascular, enteral, respiratory, epidural and intrathecal (spinal) delivery systems. These delivery systems frequently employ fittings called Luer connectors to link various system components. The male and female components of Luer connectors join together to create secure yet detachable leak-proof connections. Multiple connections between medical devices and tubing are common in patient care. Today, Luer connectors are used worldwide to connect a variety of vascular, enteral, respiratory, epidural, and intrathecal medical devices, components, and accessories.

Unfortunately, the ubiquitous nature of the Luer connector design allows for connection between unrelated delivery systems (e.g., vascular, enteral, respiratory, epidural, and intrathecal medical devices, components, and accessories). Because Luer connectors are ubiquitous, easy-to-use and

compatible between different delivery systems, patient care staff can inadvertently connect wrong systems together, causing medication or other fluids to be delivered through the wrong route. Numerous such errors have been documented, including many that have caused serious patient injuries and deaths.

3. ISO standards development process. According to its website,

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the ISO develops and publishes international standards and is comprised of a network of the national standards institutes of 161 countries. ISO launches the development of new standards in response to sectors and stakeholders that express a clearly established need for them. To be accepted for development, a proposed work item must receive the majority support of the participating members of the ISO technical committee, which, among other criteria, verifies the "global relevance" of the proposed item - this means that it indeed responds to an international need and will eventually be suitable for implementation on as broad a basis as possible worldwide. ISO standards are developed by technical committees comprising experts from the industrial, technical and business sectors which have asked for the standards. These experts may be joined by representatives of government agencies, testing laboratories, consumer associations, non-governmental organizations and academic circles.

4. Prior legislation. SB 158 (Flores), Chapter 294, Statutes of 2008, among other provisions, requires hospitals to institute a patient safety plan for the purpose of improving the health and safety of patients and reducing preventable patient safety events. Prohibits, beginning January 1, 2011, general acute care, acute psychiatric, and special hospitals from using an intravenous connection, epidural connection, or enteral feeding connection that would fit into a connection port other than the type for which it was intended, with exceptions, as specified.

AB 818 (Hernandez), Chapter 476, Statutes of 2009, delayed the January 1, 2011, implementation date of SB 158 to 36 months after the publication of a new design standard or January 1, 2014, whichever occurs first, for epidural connections, and to 24 months after the publication of new design standards or January 1, 2013, whichever occurs first, for intravenous or enteral connections. AB 818 also required the Advanced Medical Technology Association to provide the Legislature with an annual report on the progress of the ISO in developing the new design standards and required hospitals to include in their patient safety plan measures to prevent adverse events associated with misconnecting intravenous, enteral feeding, and epidural lines.

5. Support. This bill is sponsored by the Advanced Medical Technology Association (AdvaMed), which states that this bill

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will promote patient safety by ensuring that the international standards process begun by the ISO will have sufficient time to create standardized designs for the basic Luer and enteral, epidural and IV connectors. AdvaMed states that the January 1, 2016, date will allow sufficient time to perform this rigorous and critical process, while also allowing sufficient time for device makers to get FDA approval of the new designs and bring their products to market.

AdvaMed states that according to the Association for the Advancement of Medical Instrumentation, the secretariat of the ISO Working Group, final standards are not expected to be published until the first half of 2014. Because the ISO drafting process is still underway, there is no way for anyone to meet the current deadline. Absent an extension to allow these new design standards to be developed, the wrong outcome could lead to a far more dangerous health care environment than what currently exists today, fostering unintended consequences, possibly creating new risks, or creating a solution that could not be manufactured cost effectively or would be too complicated for users.

6. Opposition. The California Nurses Association (CNA) is opposed to this bill, stating that it would needlessly prolong prohibitions against the use of medically unsafe connectors for epidural, intravenous and enteral tubing. CNA points to the recent death of a cancer patient at Alta Bates Summit Hospital when CNA nurses were locked out by the employer and a replacement nurse hired by the hospital placed a liquid feeding meant for a feeding tube in the patient's stomach into the patient's intravenous line. According to CNA, medical devices that are currently available can significantly decrease the likelihood of connection errors and the use of

these protective device requirements should be implemented by the dates in current law. CNA states that the process of improvement is an ongoing one but one that should not be delayed by thinly veiled attempts by the hospital industry to increase profits in the guise of awaiting international consensus.

SUPPORT AND OPPOSITION :

Support: AdvaMed (sponsor)
Abbott Laboratories
American Society for Parenteral and Enteral Nutrition
Baxter
BayBio

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BD
BIOCOM
Boston Scientific
California Association of Nurse Anesthetists, Inc.
California Healthcare Institute
California Society of Anesthesiologists
Covidien
Hospira
I-Flow LLC
Infusion Nurses Society
Institute for Safe Medication Practices
Kimberly-Clark
Nestle HealthCare Nutrition, Inc.
Oley Foundation
Philips Electronics

Oppose: California Nurses Association

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