130th MAINE LEGISLATURE

FIRST REGULAR SESSION-2021

Legislative Document	**No. 804**
S.P. 119	In Senate, March 5, 2021

An Act To Require Notice for Orthopedic Medical Device Recalls

Reference to the Committee on Innovation, Development, Economic Advancement and Business suggested and ordered printed.

DAREK M. GRANT
Secretary of the Senate

Presented by Senator KEIM of Oxford.
Cosponsored by Representative ARFORD of Brunswick and
Senators: BLACK of Franklin, CLAXTON of Androscoggin, STEWART of Aroostook, WOODSOME of York, Representatives: JAVNER of Chester, MADIGAN of Waterville, WHITE of Waterville, ZAGER of Portland.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 10 MRSA c. 232 is enacted to read:

CHAPTER 232

NOTIFICATION OF RECALL OF ORTHOPEDIC MEDICAL DEVICES

§1500-N. Notification of recall of orthopedic medical devices

1. Definitions. As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Firm" means the manufacturer or seller of an orthopedic medical device.

B. "Health care entity" means a hospital or ambulatory surgical facility as defined in Title 22, section 1812-E that is located in this State and that purchases an orthopedic medical device from a firm.

C. "Market withdrawal" has the same meaning as in 21 Code of Federal Regulations, Section 7.3 (2019).

D. "Orthopedic medical device" means any device described in 21 Code of Federal Regulations, Part 888.

E. "Recall" has the same meaning as in 21 Code of Federal Regulations, Section 7.3 (2019).

2. Patient notification required. Within 30 days after a health care entity receives notification of a recall or market withdrawal of an orthopedic medical device that it has provided to a patient, the health care entity shall provide a written notice to the patient of the recall or market withdrawal that includes the following information:

A. Identification of the specific orthopedic medical device, including, if applicable, the lot number, code and serial number and any other pertinent descriptive information to enable accurate and immediate identification of the orthopedic medical device;

B. A concise explanation of the reason for the recall or market withdrawal, to the extent known, and the hazards posed by the orthopedic medical device, if any;

C. Specific action steps that the firm, health care entity or United States Food and Drug Administration advises the patient to take with respect to the orthopedic medical device; and

D. A point of contact for the patient to obtain further information about the recall or market withdrawal and action steps under paragraph C.

3. Civil violation. An individual or health care entity that violates this chapter commits a civil violation. The following penalties apply to violations of this chapter.

A. An individual who violates this chapter commits a civil violation for which a fine of not less than $500 and not more than $5,000 may be adjudged for each violation.

B. A health care entity that violates this chapter commits a civil violation for which a fine of not less than $2,000 and not more than $15,000 may be adjudged for each violation.

SUMMARY

This bill requires a hospital or ambulatory surgical facility to notify patients when the hospital or ambulatory surgical facility receives notice that an orthopedic medical device that the hospital or ambulatory surgical facility has provided to a patient has been subjected to market withdrawal or United States Food and Drug Administration requested recall. Notice must be provided to the patient in writing within 30 days and include identification of the specific device, a concise explanation of the reason for the recall and the hazards involved, if any, specific action steps and a point of contact for the patient.

The bill provides for a civil violation if an individual or entity fails to provide the notification. An individual is subject to a fine of not less than $500 and not more than $5,000 for each violation, and an entity is subject to a fine of not less than $2,000 and not more than $15,000 for each violation.