L.D. 804

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INNOVATION, DEVELOPMENT, ECONOMIC ADVANCEMENT AND BUSINESS

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STATE OF MAINE

SENATE

130TH LEGISLATURE

FIRST SPECIAL SESSION

COMMITTEE AMENDMENT " " to S.P. 119, L.D. 804, "An Act To Require Notice for Orthopedic Medical Device Recalls"

Amend the bill by striking out everything after the enacting clause and inserting the following:

'**Sec. 1. 22 MRSA c. 256-A** is enacted to read:

CHAPTER 256-A

ORTHOPEDIC MEDICAL DEVICE RECALLS

§1431. Notification of recall of orthopedic medical devices

Any hospital or ambulatory surgical facility, as defined in section 1812-E, that is contacted by a manufacturer of an orthopedic medical device, as described in 21 Code of Federal Regulations, Part 888, that is subject to a United States Food and Drug Administration recall or market withdrawal, as defined in 21 Code of Federal Regulations, Section 7.3 (2019), shall contact any patient who received the device consistent with the recall strategy as defined in 21 Code of Federal Regulations, Section 7.3 (2019).'

Amend the bill by relettering or renumbering any nonconsecutive Part letter or section number to read consecutively.

SUMMARY

This amendment, which is the minority report of the committee, replaces the bill. The amendment requires hospitals and ambulatory surgical facilities to notify patients who have received an orthopedic medical device that is subject to a United States Food and Drug Administration recall or market withdrawal in a manner consistent with the recall strategy in federal regulations.