Legislative Analysis

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PROHIBIT REUSE OF SINGLE-USE MEDICAL DEVICES

House Bill 5825 as enrolled
Public Act 26 of 2010
Sponsor: Rep. Dian Slavens

Senate Bill 528 as enrolled
Public Act 25 of 2010
Sponsor: Sen. Bill Hardiman

House Committee: Health Policy
Senate Committee: Health Policy

Second Analysis (10-15-10)

BRIEF SUMMARY: The bills would prohibit a person in a regulated health profession, or a health facility or agency, from using a previously-used, single use product more than once, establish penalties for a violation, and include the penalty within the sentencing guidelines.

FISCAL IMPACT: The bills would have a fiscal impact on the state, as discussed later in the analysis.

THE APPARENT PROBLEM:

Several years ago, a Grand Rapids dermatologist was charged with federal insurance fraud. During the trial, the defendant doctor played a video of a surgery he performed in the hopes that it would prove he really had performed the billed procedures. The expert witness for the prosecution noticed something else, however. He noticed that the sutures were shorter than they should have been, indicating that the defendant was reusing sutures.

A subsequent investigation revealed that not only was the doctor reusing sutures, but also hypodermic syringes and needles, scalpels, and gloves. Health officials estimate that almost 5,000 people were exposed to hepatitis B and C and HIV. Though the doctor was later convicted on the insurance fraud charges, reusing medical equipment meant for a single use did not violate any existing federal or state laws. Legislation has been introduced to make it a crime to reuse medical equipment intended for only one use.

THE CONTENT OF THE BILLS:

Senate Bill 528 would prohibit a person in a regulated health profession from using a previously-used, single use product more than once and establish administrative penalties for a violation. House Bill 5825 would include the penalty for a violation within the sentencing guidelines.

Senate Bill 528 would add a new section to the Public Health Code (MCL 333.20153) to prohibit a health care provider from knowingly reusing, recycling, refurbishing for reuse,

or providing for reuse a single-use device. "Single use device" would mean a medical device intended for one use or one procedure on a human patient, and would include any device marked "single-use device."

A violation would be a felony punishable by imprisonment for not more than 10 years and/or a fine of not more than $50,000. A violation by a health care professional would be considered a violation of Article 15 of the code and would subject the health care professional to administrative action (which can include additional fines and/or license sanctions) under Sections 16221(h) and 16226.

Applicability. The bill would apply to a health facility or agency that, or a health professional who, utilized single use devices in furnishing medical or surgical treatment or care to human patients. "Health professional" would mean an individual registered, certified, or otherwise authorized to engage in a health profession under Article 15 of the Public Health Code, but would exclude dentists, dental hygienists, or dental assistants, as well as veterinarians or veterinary technicians.

[The health professions regulated under Article 15 are acupuncture, chiropractic, dentistry, audiology, marriage and family therapy, medicine, nursing, optometry, osteopathic medicine and surgery, speech-language pathology, pharmacy, physical therapy, athletic training, massage therapy, podiatric medicine and surgery, nursing home administrator, counseling, psychology, occupational therapists, dietetics and nutrition, sanitarians, social work, respiratory care, and veterinary medicine.]

Exemptions. The bill would not apply to a health care provider that utilized, recycled, or reprocessed for utilization, or provided for utilization, a single-use device that had been reprocessed by a federally registered and regulated reprocessor.

"Reprocessed" would mean, with respect to a single-use device, an original device that had previously been used on a human patient and had been subjected to additional processing and manufacturing for the purpose of additional use on a different patient. The term would include the subsequent processing and manufacture of a reprocessed single-use device and any single-use device that met the definition in the bill without regard to any description of the device used by the manufacturer of the device or other persons; this would include a description that used the term "recycled," "refurbished," or "reused" rather than the term "reprocessed." In addition, "reprocessed" would not include a disposable or single-use device that had been opened but not used on a person.

The bill would also not apply to a health care provider that utilized an opened, but unused, single-use device for which the sterility had been breached or compromised and which met all of the following requirements:

- The single-use device had not been used on a human patient and had not been in contact with blood or bodily fluids.
- The single-use device had been resterilized.
- The single-use device was utilized on the same human patient in an emergency situation.

House Bill 5825 would amend the Code of Criminal Procedure (MCL 777.13n) to specify that the reuse of a single use medical product would be a Class D felony against the public safety with a maximum term of imprisonment of 10 years. The bill is tie-barred to Senate Bill 528.

FISCAL INFORMATION:

Senate Bill 528 may have fiscal implications for the Bureau of Health Professions and the Bureau of Health Systems in the Department of Community Health. Some additional costs may be incurred by the Department related to enforcement and violations for licensed health professions, and health facilities or agencies as defined in the Public Health Code. If these functions cannot be performed with existing personnel and resources, each additional regulatory FTE required to carry out the functions of the bill would be at a total cost of approximately $80,000 - $100,000.

If the changes made by the bill result in reduced infections or other consequential illness, over time the bill may have the fiscal impact of reducing state costs for related medical services for state employees and Medicaid participants.

Under the bill, any fines collected from violators would be deposited to the state's General Fund.

The impact of **House Bill 5825**, as introduced, specifies that a violation of the provision added by **Senate Bill 528** is a Class D felony punishable by up to 10 years in prison.

The fiscal impact on state and local correctional systems by the bills would depend on how they affected the numbers of felony convictions and severity of sentences. There are no data to indicate how many offenders might be affected by the bills. To the extent that the bills increased the numbers of felony sentences, the state could incur increased costs of incarceration or felony probation supervision. The average appropriated cost of prison incarceration is roughly $33,000 per prisoner per year, a figure that includes various fixed administrative and operational costs. Costs of parole and probation supervision, exclusive of the cost of electronic tether, average about $2,100 per supervised offender per year. To the extent that more offenders were sentenced to jail, affected counties could incur increased costs; jail costs vary with jurisdiction. The felony offense of reusing a single-use medical product would be a Class D offense against public safety. Exclusive of sentences for habitual offenders, the guidelines-recommended minimum sentence for a Class D offense varies from 0-6 months, for which a nonprison sanction is required, to 43-76 months, for which a prison sentence is required.

Any increase in penal fine revenues would benefit local libraries, which are the constitutionally-designated recipients of those revenues.

ARGUMENTS:

For:

The bills fill a gap in current law that fails to criminalize the deliberate reuse of medical devices meant to be used one time on one human patient. The practices of the Grand

Rapids doctor described earlier unnecessarily exposed patients to serious and life-threatening infections and diseases, caused untold mental anguish among his former patients, and cost taxpayers a lot of money in departmental investigations and notifications to the former patients. Yet, the conduct was not unlawful.

The bills would address the concern by making it clear that any doctor or other health professional who engaged in similar practices would face license sanctions, a felony record, up to a decade in prison, and could be ordered to pay a hefty fine. The hope is that the bills would be a strong deterrent in discouraging similar conduct and also provide an appropriate punishment should a health professional fail to abide by standard medical practices.

Response:

When House Bill 4940 (a bill similar to SB 528) was reported from committee last year, there was concern that the bill would be problematic for home health care providers. Many insurance policies limit the number of certain types of medical equipment covered during a specific period. As a result, it is not uncommon for home health aides and nurses to clean and reuse, on the same patient, equipment such as tracheotomy tubes and feeding tubes until such time as the benefit renews. Many patients and their families simply cannot afford the out-of-pocket costs that otherwise would be incurred. The association representing nurses requested at that time that the language be further tweaked to address this concern and also to distinguish between single use and disposable medical equipment, especially as these issues pertain to the delivery of home health services. It is unclear if Senate Bill 528, which would exempt single-use devices used on the same human patient in an emergency, is sufficient to address these concerns.

For:

According to the Michigan Health & Hospital Association, the Federal Food and Drug Administration began regulating the practice of reprocessing and reusing medical devices in 2001. The FDA has deemed certain types of medical devices that are labeled as single use to be reusable, such as blood pressure cuffs, oxygen masks, saw blades (used during surgery to cut hard or soft tissues), and laparoscopic scissors and shears (used during general and OB/GYN surgery). The devices are tested during reprocessing to ensure their safe reuse. Exempting the devices approved by the FDA to be reprocessed and reused from the prohibition contained in Senate Bill 528 will enable hospitals to reduce both medical equipment costs and hazardous waste.

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