701 Pennsylvania Avenue, Ste. 800
Washington, DC 20004–2654
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

AdvaMed
Advanced Medical Technology Association

February 9, 2022

Senator Jarrett Keohokalole
Chair, Senate Committee on Health
Hawai'i State Senate
Hawai'i State Capitol, Room 205
Honolulu, HI 96813

Re: SB 760 – Medical Device Repair Mandate – Oppose

Senator Keohokalole:

I appreciate the opportunity to provide written testimony today on behalf of the Advanced Medical Technology Association (AdvaMed), the world's largest association representing manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members range from the largest to the smallest medical technology innovators and companies.

Today I am writing to express our respectful opposition to Senate Bill 760, that would compromise patient safety through requiring medical device manufacturers to share repair and design information with third-party servicing entities. Without appropriate training on complex medical devices, patient health and safety may be put at risk. that have not received appropriate training for the sophistication of the technology. The legislation also fails to require third parties to comply with Food and Drug Administration (FDA) regulations or reporting of adverse events.

Patient Safety is Paramount

Original Equipment Manufacturers (OEMs) are required to adhere to federal regulations – more specifically the Quality System Regulation (QSR)[1] - that require sufficient personnel and training to service them, as well as maintenance of service records on the device, maintenance of training records, and reporting of any malfunctions or defects associated with the serviced device. These requirements are extended to anyone authorized by the OEM, including many third-party service providers, who service their medical technology. These regulations help protect patient safety throughout the design, servicing, and repair process and ensure that regulators and manufacturers are made aware of malfunctions, serious injuries, and other issues in a timely fashion.

Non-authorized third-party servicers are not subject to these same requirements. For this reason, there is no reliable mechanism for OEMs to know how many product failures are due to inadequate, unauthorized servicing and repairs. Of note, FDA issued a report documenting more than 4,300 adverse events – including 294 serious injuries and 40 deaths – that could be attributed to unauthorized servicers. This bill would exacerbate the situation by further enabling 'invisible repairs' that are totally unknown to the OEM or the FDA, adding further complexity to tracking and reporting the quality of work by non-authorized third-party servicers.

Access to Service Not Impeded

As touched on previously, OEMs provide extensive training for their employees and typically make this training available to customers and other third-party servicing entities as part of a coordinated repair strategy. The extensive number of available technicians authorized by OEMs has helped to prevent any credible reports of systemic repair shortages – even during the throes of the pandemic – and to ensure patients remain safe during the use of these complex medical technologies. Any intermittent shortages are a function of the global supply chain and impact access to specific parts no matter the purchaser.

Further, purchasers of medical technology often have many options and are in no way required to use an authorized servicer. Purchasers can take advantage of in-house options for servicing or are free to hire any third-party service company they desire. However, the fact remains that, regarding complex medical technology, authorized servicers provide fast, excellent, and high-quality service and repair – saving customers both time and money through reduced downtimes and optimally-functioning technology and ensuring safe and effective devices for patients.

Innovation and Patient Safety Keyed by Intellectual Property Protection

Medical technology OEMs invest significant resources in research and development to bring to market technologies benefiting patients. Unfortunately, this legislation cripples the intellectual property protections guarding patient safety and patient data in addition to harming the protections in their investment by encouraging piracy of proprietary documentation, including documents related to cybersecurity, by purporting to protect intellectual property but instead relying on circular language.

The requirements of Section 3 state that manufacturers must provide on "fair and reasonable terms, documentation, parts, and tools...training materials and courses relating to the operation, inspection, diagnosis, maintenance, and repair of powered medical equipment." Later it reads that "nothing in this chapter shall be construed to require an original equipment manufacturer to divulge a trade secret...except as necessary to provide documentation, parts, tools, and training courses and materials on fair and reasonable terms." In many cases, these provisions directly conflict. Trade secrets would be among what would be required to be provided under the earlier provision, (i.e., the first provision would force the disclosure of trade secrets to an entity that has no contractual relationship to the OEM to protect the IP. Significant litigation is the likely result under any attempt to enforce either provision.

The forced disclosure of intellectual property to an entity who is not in a contractual relationship with the OEM decimates the security around maintaining its safe and effective operation in

addition to compromising patient data, as any individual can start an independent repair business in the state. Since an OEM's proprietary information – process, methods, technical specifications, or designs – could then be sold through sites such as iFixit or other similar forums, incentivizing piracy and discouraging investment in the very medical technology that is improving safety, and dramatically driving down costs, for patients. This legislation would directly increase the risk of malfunctions (when used by untrained servicers) and nefarious cybersecurity hacks, both of which could jeopardize patient safety through improper operation (impacting treatment and diagnosis). Similarly, the forced disclosure of this proprietary information by legislation would facilitate unauthorized access to patient data.

This legislation would also create the incentive to shift many future medical technology offerings to be available only under lease arrangements to ensure patient safety and protect intellectual property, reducing the flexibility and breadth of arrangements available to providers today.

Conclusion

Thank you for considering our perspective on this complicated issue. Our members bear a significant responsibility to the patients, businesses, governments, and individual consumers that depend on us to protect the safety and security of their medical products, as well as the sensitive data that they contain. We are committed to working with the legislature to promote patient safety, digital privacy and security, while resisting unwarranted intervention in the marketplace with one-sized-fits-all mandates that compromise patient safety in the state.

Sincerely,

Bobby Patrick
Vice President, State Government and Regional Affairs
Advanced Medical Technology Association (AdvaMed)

cc: Members of the Hawai'i Senate Committee on Health
Senator Chris Lee, Senate District 25

MITA®
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA®

1300 North 17th Street ▪ Suite 900
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

February 8, 2022

The Honorable Jarrett Keohokalole, Chairperson
415 South Beretania St. Room 205
Honolulu, HI 96813

Re: Opposition to S.B. 760

Dear Chairperson Keohokalole and Committee members:

As the leading trade association representing manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices, the Medical Imaging & Technology Alliance (MITA) opposes S.B. 760. MITA urges the Committee **not** to advance this bill given the risks it would create for patient safety, cybersecurity, vulnerability to legal challenge, and significant new and unnecessary costs the bill would create for the State of Hawaii.

Medical device servicing must be safe and effective to protect patient safety

Servicing a medical device is a complex activity that poses a potential range of serious risks to both patients and operators if performed improperly. Uncontrolled distribution and use of proprietary, highly technical service materials by entities that are not required to have appropriate processes and controls in place could lead to improper servicing of a medical device, dramatically increasing risks to patient safety, device performance, and cybersecurity. Safe and effective servicing is not merely a function of acquiring certain documentation or materials—it is the full implementation of and adherence to a set of policies, practices, and procedures that consistently return the device to safe and effective operation.

Medical imaging device servicing requires a high level of technical expertise. This training needs to be regularly updated to reflect knowledge of the latest products, including software and hardware, and a deep understanding of and adherence to current best practices. Operating within a quality management system (QMS) conformant with 21 CFR 820 ensures that devices consistently meet applicable requirements and specifications.

Not only are there potential serious safety concerns with this bill but these concerns would likely increase costs to State medical facilities, in the form of increased litigation stemming from the increased patient safety concerns, increase in medical malpractice insurance, or both. So, in addition to the direct cost to taxpayers in both of these situations, there are also the indirect costs to taxpayers through the likely substantial increases in health insurance and health care programs.

Medical devices are FDA Regulated

Medical device original equipment manufacturers (OEMs) and their authorized service providers are regulated by the United States Food and Drug Administration (FDA) and must adhere to rigorous quality, safety, and regulatory requirements, including 21 CFR 820, when performing maintenance and repair. Independent device service providers are not held to the same rules as OEMs (and their authorized repair

providers) when they perform maintenance and repair activities on the same sorts of advanced technology systems. In fact, independent medical device servicing businesses are not currently held accountable for the safety or quality of their work by any authority.

Only OEMs are held by the FDA to high regulatory requirements, including 21 CFR 820, with respect to post-sale servicing of medical imaging equipment. Non-OEM entities are not held to the same quality, safety, and regulatory requirements as are OEMs. Given the ongoing consideration at the federal level, we believe that a patchwork of state laws would directly conflict with the unarguable need for consistency in medical device servicing.

The medical device servicing market is robust and thriving

A recent study estimated that the total number of firms performing medical device servicing in the United States is between 16,520 and 20,830.[1] Furthermore, a separate study estimated that there are 6,500 medical device manufacturers in the U.S.[2] This is clear proof of a thriving marketplace for medical device servicers.

There are a variety of valid business models for medical imaging device servicing. Service models and contractual terms are established at the point of sale, enabling health care facilities to decide what level of servicing they would like to purchase from the manufacturer versus take on themselves or contract out to a third party.

Many OEMs choose to service their own devices. Other medical device companies choose to partner with ISOs to extend their ability to keep their devices operating safely and effectively. Many OEMs establish a contractual relationship to make servicing materials and parts available. Each kind of relationship also differs in its specifics with varying kinds and degrees of support provided under a variety of contractual arrangements.

Given this, purchasers of medical devices and associated servicing activities have a sufficient amount of information to make informed buying decisions.

S.B. 760 would create new and unnecessary cybersecurity risks

Whenever software is installed or adjusted for a medical device, or if software tools are used to access a device for diagnostic and maintenance purposes, the integrity of the software may be compromised. In 2020 alone, 92 individual ransomware attacks occurred that cost an estimated $20 billion, affected over 600 separate clinics, hospitals, and organizations, and jeopardized more than 18 million patient records. Unvalidated software without confirmed authenticity or system integration may present significant potential security vulnerabilities and operational issues. Additionally, expanded and uncontrolled access to medical device operating systems and software applications creates the potential for increased cybersecurity risks, as the opportunity to intentionally or unintentionally introduce security vulnerabilities to the device and to any networks to which the device is connected (e.g. hospital) also expands.

This Legislation Would be Unconstitutional

This bill, if enacted into law, would violate the U.S. Constitution and would be vulnerable to legal challenge. The law would be preempted by federal law, it would be an unconstitutional regulation of

[1] https://www.fda.gov/media/113431/download
[2] https://www.themadeinamericamovement.com/reshoring/u-s-medical-device-industry/

interstate commerce, would amount to an unconstitutional taking of property, would unconstitutionally compel speech, and would interfere with existing contracts.

Preemption Under Federal Law

The federal Supremacy Clause—art. VI, cl. 2—gives Congress "the power to preempt state law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). Federal law need not expressly displace state law to have preemptive effect. Rather, "state laws are preempted when they conflict with federal law," either because compliance with both federal and state law is "impossibl[e]" or because state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v. United States*, 567 U.S. 387, 399 (2012). The proposed bill conflicts with, and is therefore preempted by, multiple federal statutory schemes:

1. Patent law. Federal patent statutes embody "a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). The foundational right granted under federal patent law is the right "to exclude others from making, using, or selling embodiments of their invention." *Biotechnology Indus. Org. v. Dist. of Columbia* ("*BIO*"), 496 F.3d 1362, 1372 (Fed. Cir. 2007).

States' attempts to abrogate or diminish federal patent rights of exclusivity are preempted. In *BIO*, for example, the U.S. Court of Appeals for the Federal Circuit struck down a District of Columbia law restricting prices of patented drugs because it conflicted with, and was therefore preempted by, federal patent law. 496 F.3d at 1374. The court explained that D.C.'s restrictions conflicted with federal patent law because their effect was to "diminish[] the reward to patentees in order to provide greater benefit to District drug consumers." *Id.* The court reasoned that congressional patent policy balanced the competing interests of "reward[ing] innovators with higher profits and … keep[ing] prices reasonable for consumers" by granting innovators a statutory monopoly of limited duration. *Id.* at 1373. The challenged statute purported "to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs" by restraining prices that D.C. deemed excessive. *Id.* at 1374.

This bill raises similar constitutional concerns. Medical equipment manufacturers—like the pharmaceutical manufacturers at issue in *BIO*—invest enormous sums in research and development, both for their equipment and for the various tools that enable their safe and effective repair.

This bill would also circumvent (and therefore conflict with) federal protections by requiring OEMs to provide "documentation, parts, and tools, inclusive of any updates to information or embedded software." Rather than allowing OEMs to license and distribute their creations to repair providers of their choosing, the bill would compel OEMs to give away their protected property and information, thereby nullifying OEM's statutory rights of exclusivity and financial rewards that promoted their innovation in the first place. That state-law regime undermines the "complex balance of economic forces and regulatory exclusivity designed to encourage and reward the innovation of, research, and development" of new medical technologies and the advanced systems that enable their safe and effective maintenance. *BIO*, 496 F.3d at 1366.

2. Copyright. Similar principles support a preemption argument based on federal copyright law. The copyright statutes reflect Congress's efforts to strike a balance between innovation and public access for creative works by prohibiting the unauthorized use of copyrighted material for a fixed term following the work's publication. *See Eldred v. Ashcroft*, 537 U.S. 186, 212 (2003). Copyright laws have long been held to cover written manuals and other materials reflecting the "original selection or arrangement of facts." *Feist Publications, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 350 (1991).

Under federal law, OEMs—just like other media creators—have the right to limit the reproduction and access of their copyright-protected repair and training materials, which like their inventions are the product of significant time and investment. By forcing OEMs to provide this information—even under "fair and reasonable terms"—this bill would upset the federal regime of exclusivity. The bill effectively imposes a state compulsory licensing regime. But when the federal copyright statutes permit such compulsory licensing, they do so expressly. *See* 17 U.S.C. § 155.

Besides erasing OEM's rights of exclusivity, this bill circumvents protective measures manufacturers use to guard their own intellectual property. For that reason, the bill is preempted by the Digital Millennium Copyright Act (DMCA), which Congress enacted to modernize and strengthen copyright protection for digital creations. The DMCA is the exclusive framework governing protective measures against copyright infringement.

3. Trade Secrets. Independently, this bill could require that manufacturers divulge their trade secrets, which conflicts with the federal Defend Trade Secrets Act of 2016 (DTSA). The bill provides: "Nothing in this Act shall be construed to require an original equipment manufacturer to divulge a trade secret to an owner or an independent service provider *except as necessary to provide documentation, parts, and tools on fair and reasonable terms*." This exception swallows the rule. Congress enacted the DTSA to "improv[e] trade secret protection" and thereby to "incentivize future innovation while protecting and encouraging the creation of American jobs." S. Rep. No. 114-220, at 3. To further those goals, DTSA prohibits the misappropriation of trade secrets, imposes criminal penalties for violations, and provides the holders of trade secrets with a range of remedies to prevent misappropriation, including private suits for injunctions. *See* 18 U.S.C. § 1836(b)(3). State laws compelling the unauthorized disclosure of trade secrets undercut the protective purpose of the DTSA, and thus raise preemption questions. This bill strips protection from OEM's repair-related information, much of which is proprietary and sensitive and therefore falls within the definition of a trade secret under state and federal law.

Regulation of Interstate Commerce

The Commerce Clause gives Congress the power "[t]o regulate Commerce with foreign Nations, and among the several States." U.S. Const., Art. I, § 8, cl. 3. The Supreme Court has "long interpreted the Commerce Clause as an implicit restraint on state authority, even in the absence of a conflicting federal statute." *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007). This "further, negative command" is "known as the dormant Commerce Clause." *Comptroller of the Treasury v. Wynne*, 135 S. Ct. 1787, 1794 (2015). As relevant here, a state law can violate the dormant Commerce Clause either by directly regulating out-of-state conduct or by imposing excessive burdens on interstate commerce. This bill would do both.

This bill would *directly* regulate commerce outside the state. A state law applies "extraterritorially" if it either expressly applies to out-of-state commerce or has that "practical effect." *Assoc. for Accessible Med. v. Frosh (AAM)*, 887 F.3d 664, 668 (4th Cir. 2018). Courts generally invalidate such laws "without further inquiry." *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986). In *AAM*, for example, the U.S. Court of Appeals for the Fourth Circuit struck down a Maryland law that banned "price gouging" because although the statute by its terms applied only to pharmaceuticals "made available for sale" in Maryland, it had the "practical effect" of regulating prices in "upstream" transactions occurring "almost exclusively" outside of the state. 887 F.3d at 672-73 (citing *Brown-Forman*, 476 U.S. at 580). Although price controls like those struck down in *AAM* quintessentially violate the extraterritoriality rule, the rule also forbids non-price regulations that affect commerce nationwide. *See, e.g., Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1323-25 (9th Cir. 2015) (en banc).

Under these principles, this bill would have an unlawful extraterritorial effect. In effect, the State is commanding out-of-state businesses to provide a host of materials and services to in-state businesses, simply because the out-of-state business's products have wound up in the state. In addition, the bill would compel manufacturers to disclose sensitive and proprietary information. Once unauthorized third parties gain access to that information, its value, which inheres in its secrecy, is lost forever—not just within the state but *nationwide*. Under the Commerce Clause, the state lacks any "valid … authority" to "project[] its legislation into other states." *Brown-Forman,* 476 U.S. at 583-84.

Setting extraterritoriality aside, the bill raises concerns under the so-called "*Pike* balancing test" because it would impose burdens on interstate commerce that are "clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). Medical device manufacturers sell their lifesaving devices to medical providers across the nation. Once patented tools and technologies are made available in the marketplace and copyrighted materials are freely accessible, that material loses protection everywhere.

Taking of Property

Under the Fifth Amendment, "private property [shall not] be taken for public use, without just compensation." That prohibition prevents public officials from taking or destroying the value of private property without providing adequate compensation. The Supreme Court has long held that the Takings Clause protects intellectual property, including trade secrets, just as it does physical property. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002-04 (1984). Courts apply two modes of analysis in reviewing takings challenges, depending on whether the challenged taking is "categorical" or "regulatory." This bill triggers both modes of analysis.

The bill constitutes an unlawful regulatory taking under the analysis set out in *Penn Central Transportation Co. v. City of New York*, 438 U.S. 104 (1978). *Penn Central* describes three factors relevant to an analysis of a regulatory taking: (1) the economic impact of the regulation on the claimant, (2) the extent to which the regulation interfered with the claimant's investment-backed expectations, and (3) the character of the government action. *Id.* at 124. Applying these factors, the bill is unconstitutional. OEMs invest enormous sums in the development of their products and in the tools and material necessary for safe and effective repair. They do so with expectations about their ability to exclude, through contracts and under federal patent and copyright laws, access by unauthorized and unqualified individuals. The economic impact of stripping away OEM's rights of exclusivity will be immediate and significant.

Compelled Speech

The bill also compels OEMs to disclose a broad array of materials, including written documentation and service access methods, to independent service repair providers who have no commercial relationship with the OEM. In doing so, the bill violates the First Amendment's guarantee of the freedom of speech. The First Amendment has long been held to "prohibit[] the government from telling people what they must say." *Rumsfeld v. Forum for Acad. & Inst. Rights, Inc.*, 547 U.S. 47, 61 (2006).

The bill violates that principle by compelling OEMs to divulge commercially sensitive information about their products. Because the bill targets a discrete set of actors (medical equipment manufacturers) and compels the disclosure of a specific type of content (that which the State deems necessary for repairing medical equipment), the bill is a "speaker-based" and "content-based" mandate, meaning that a reviewing court should apply heightened scrutiny. *See Sorrell v. IMS Health Inc.*, 564 U.S. 552, 573 (2011); *Reed v. Town of Gilbert,* 135 S. Ct. 2218, 2226 (2015). Under heightened scrutiny, such laws "are presumptively unconstitutional." *Reed,* 135 S. Ct. at 163.

Requiring OEMs to turn over all manner of repair-related information, parts, and tools—even at a "fair and reasonable" price—is not "narrowly tailored" to serve a sufficiently "compelling" government interest. *Id.* at 171. To be sure, the State would also likely assert that the law is justified by public-health concerns stemming from alleged delays in repairing equipment or higher prices for repairs. But while public-health concerns *can* be "compelling," the government must point to a specific problem that justifies "differentiation" between medical equipment manufacturers and other entities that support public-health infrastructure. *Id.* Moreover, the State may need to define its interest with greater specificity in order to assess whether the treatment fits the State's need. Even if the bill furthered a substantial state interest, the bill is not narrowly tailored because it unnecessarily threatens the permanent destruction of OEM's valuable intellectual property. There are also alternative ways that the State could further its interests.

The State could respond that the bill either (1) does not regulate speech at all and instead requires the provision of products and services that manufacturers already offer, or alternatively (2) regulates "commercial speech" and is therefore subject to lesser scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980). Neither argument would have merit. First, the bill does not simply require manufacturers to perform services, but rather requires them to disseminate information and materials about the use of their products. These forms of information are expressive (as suggested by their copyright protection) and thus there is a strong argument that compelling the disclosure of this information is compelling *speech*: "The law here, like the Vermont law in *Sorrell*, 'does not simply have an effect on speech, but is directed at certain content and is aimed at particular speakers.'" *APAC*, 140 S. Ct. at 2347 (quoting *Sorrell*, 564 U.S. at 567). Second, the notion that the bill compels only "commercial speech" has lost significant force following the Supreme Court's recent decision in *APAC*. There, the plurality opinion applied strict scrutiny rather than *Central Hudson* in holding that Congress could not constitutionally exempt government-debt collectors from its ban on robocalls. 140 S. Ct. at 2347. Regardless, laws subject to *Central Hudson* must still be "narrowly tailored to serve a significant governmental interest," *id.* at 2356 (Sotomayor, J., concurring), and for the reasons explained above, there are credible arguments that the bill would fail that test, as well.

Interference with Contracts

Finally, the bill implicates the federal Contracts Clause, which provides that "[n]o State shall … pass any … Law impairing the Obligation of Contracts…." Art. I, § 10, cl. 1. A state law violates the Contracts Clause when it (1) operates "as a substantial impairment of a contractual relationship," and (2) is not "an appropriate and reasonable way to advance a significant and legitimate public purpose." *Sveen v. Melin*, 138 S. Ct. 1815, 1822 (2018). Existing contracts between manufacturers and medical service providers establish clear permissions and restrictions on the use of the equipment and related documents and materials. This exclusivity is a substantial component of the parties' bargain.

The express purpose and inevitable effect of the bill is to fundamentally alter those terms by abolishing the right to restrict third parties from accessing manufacturers' technology. In other words, a state law requiring protected information to be divulged to third parties substantially reduces the value of these existing negotiated contracts and thus inherently "impair[s]" them. And just as the bill is not narrowly tailored to any compelling government interest in the First Amendment context, and interferes with investment-backed expectations in the takings context, the bill arguably is not an appropriate and reasonable way to advance a significant and legitimate public purpose.

Conclusion

Our position is that all entities engaged in servicing medical devices should be held to consistent quality, safety, and regulatory requirements and that the intellectual property rights of medical device innovators must be protected. If enacted, this legislation would create new and unnecessary risks to patient safety,

devastate the IP rights of medical device innovators, and lead to costly and protracted implementation, enforcement, and litigation risk for the State of Hawaii, encumbering the State's budget. For these reasons, we urge the Committee to not advance this bill.

****

If you have any questions, please contact me or Laura Srebnik, Manager, Government Relations at lsrebnik@medicalimaging.org or 703- 841-3247.

Sincerely,

Medical Imaging & Technology Alliance

MITA is the collective voice of manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging innovations. These products include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. MITA Member company technologies are an important part of our nation's healthcare infrastructure and are essential for the screening, diagnosis, staging, managing and effectively treating patients with cancer, heart disease, neurological degeneration, and numerous other medical conditions.

PHILIPS

February 9, 2022

The Honorable Jarrett Keohokalole
Chair, Senate Committee on Health
415 S Beretania Street
Honolulu, HI 96813

Dear Senator Keohokalole,

My name is Ken Oshiro, and I am a Field Service Engineer for Philips based in Hawaii. I have been working in medical device repair and servicing since 1993. As both a constituent of this state and on behalf of Philips, **I write to voice our opposition to SB 760**, currently before the Senate Committee on Health.

Philips is a healthcare technology company focused on improving people's health and enabling better outcomes. The company provides healthcare solutions including imaging machines like MRI and CT scanners, patient monitors, among other products. Importantly, Philips has long supported patients across many of Hawaii's healthcare systems like Kaiser, Hawaii Pacific Health and Queens Medical Center.

We who work in this industry share the common goal of delivering the highest quality of healthcare, including having access to safe, reliable and clinically accurate medical equipment. Achieving skilled competency to service medical equipment requires more than having access to instruction manuals and diagnostic information. It takes a combination of traditional schooling, technical training, field mentorship, continuing education and total immersion in the solution.

I am concerned this bill gives virtually anyone the tools, intellectual property and access needed to tinker with any medical device, regardless of experience and training - and without adherence to regulatory controls and oversight. Specifically, there is no federal regulation of unauthorized, independent repair providers. There is no transparency about how independent repair providers are trained, the quality of their work or parts they use. I must follow quality management systems and adverse event reporting standards, but independent repair providers are not subject to these requirements.

More importantly, these are no longer stand alone devices. In today's connected healthcare environment, these devices share data over a health system's network and with a patient's electronic medical record making cybersecurity and patient safety of the utmost importance. My training ensures that security protocols are followed. On the other hand, non-trained service professionals may inadvertently disable key security features, which could expose connected networks to cyberattacks, viruses and hackers. For instance, if independent repair providers change systems securities, add, or update software, or change configurations, opportunities exist for unauthorized third parties to access the system and make modifications that could impact patient safety.

Independent repair providers also do not have to use tested and certified replacement parts, which could lead to suboptimal repair and device malfunction. In the world of high-pressure medical service delivery, people may unknowingly or knowingly overstep their trained capabilities or compromise standards resulting in decreased service quality and increased patient safety risks.

In addition, another concern involves the safety of the engineer who services medical devices if improperly trained. Many medical devices are complex machines, involving components that are dangerous to the operator, like those that emit radiation or high heat for example. There is a very high risk of severe injuries or even death if engineers service systems without proper training.

If the concern is free market and competition, a system exists already that gives hospitals choices. In-house biomeds and authorized third party service providers currently can receive OEM training alongside our engineers and obtain the diagnostic tools and technical documentation needed to resolve issues. In fact, we work closely with in-house biomeds across Hawaii hospitals.

To conclude, we should always strive to improve healthcare quality and patient safety, but this bill is a move backward by creating a process that would allow someone who may lack the right expertise to service complex medical equipment without any oversight or regulation.

For these reasons, I urge the Committee on Health to reject SB 760.

Sincerely,

Ken Oshiro
Field Service Engineer
Philips

February 08, 2022

The Honorable Jarrett Keohokalole, Chairperson
415 South Beretania St., Room 205
Honolulu, HI 96813

Re: Opposition to S.B. 760

Dear Chairperson Keohokalole and Committee members:

My name is Eric Eichholz, and I am submitting testimony in opposition to S.B. 760. I work for Varian, a Siemens Healthineers company, as a Field Product Specialist and I live in Honolulu. I have been with Varian for 24 years and have lived in Hawaii for 7 years. I am part of a team of engineers supporting the 11 Radiation Therapy machines used to treat cancer here in the islands.

I wanted to discuss why I think "right to repair" bill S.B 760 is not only unnecessary but could also cause patient harm. Medical device "right to repair" is not necessary in Hawaii because manufactures already have great local service engineers and authorized service providers. Our entire day is focused on the timely and successful repair of the medical devices under our purview.

You may have heard that "right to repair" is needed because there are delays in getting service for medical devices, especially during the COVID-19 Pandemic. I would like to state for the record that this could not be further from the truth. For most service calls in Oahu we can be on-site within 30 minutes and for neighbor islands we typically are onsite within 2 hours. Additionally, we ensured that these timeframes did not change during the Pandemic. I would venture to say that our customers saw zero change in response times or quality of service during the Pandemic. We know that our servicers provide the best service for our customers and because of this we know that they do not want to risk using unauthorized third parties to service their medical devices.

You may ask what the risks are for legislation to require manufactures to provide manuals, diagrams, service codes, schematics, etc. to unauthorized third parties. Unfortunately, this has the potential to cause significant patient safety concerns. Our engineers undergo significant training and certification processes to ensure we are held to a higher standard when maintaining complex medical devices. Quality service is dependent on more than just the possession of manuals and materials. It is necessary to have the same extensive training that we have and follow minimum quality, safety, and regulatory requirements that we and our authorized servicers follow to provide the high level of service that we guarantee. Without the same training and requirements unauthorized third parties could put technicians and patients at risk for serious injury. Specifically in my field, a successful cancer treatment relies on high quality imaging systems, state of the art treatment planning and verification systems, and a linear accelerator to precisely deliver radiation to the tumor area while sparing healthy tissue. This process cannot be left to chance.

There is no evidence of any issues with the current medical device servicing system in Hawaii and I fear that if this bill became law, there could be serious repercussions to patient safety. For these reasons, I and Siemens Healthineers strongly opposes S.B. 760.

Sincerely,

Eric A Eichholz

SB-760
Submitted on: 2/7/2022 2:54:30 PM
Testimony for HTH on 2/9/2022 1:35:00 PM

Submitted By	Organization	Testifier Position	Remote Testimony Requested
Deborah G. Nehmad	Individual	Support	No

Comments:

Please support