SENATE COMMITTEE ON HEALTH
Senator Dr. Richard Pan, Chair

BILL NO: SB 605
AUTHOR: Eggman
VERSION: February 18, 2021
HEARING DATE: April 14, 2021
CONSULTANT: Vincent D. Marchand

SUBJECT: Medical Device Right to Repair Act

SUMMARY: Requires a manufacturer of powered medical equipment to make available, to both owners of the powered medical equipment and independent repair providers, on fair and reasonable terms, any documentation, parts, and tools needed for purposes of inspection, diagnosis, maintenance, or repair of powered medical equipment.

Existing law:
1) Establishes the Sherman Food, Drug, and Cosmetic Law, to regulate the manufacture, production, processing, and packing of any food, drug, device, or cosmetic, enforced by the California Department of Public Health (CDPH). [HSC §109875, et seq.]

2) Permits CDPH to establish performance standards for devices that are required to be designed to provide reasonable assurance of safe and effective performance and, where appropriate, requiring the use and prescribing the form and content of labeling for the proper installation, maintenance, operation, or use of the device. However, specifies that if a performance standard is established for a device pursuant to federal law, as specified, the federal standard is the performance standard in California for the device. [HSC §111245]

3) Requires every manufacturer making an express warranty with respect to certain electronics and appliances valued at between $50 and $99.99, to make available to service and repair facilities sufficient service literature and functional parts to affect the repair of a product for at least three years after the date a product model or type was manufactured, regardless of whether the three-year period exceeds the warranty period for the product. For these same products costing in excess of $100, requires the manufacturer to make the service literature and parts available for at least seven years after the date a product was manufactured. [CIV §1793.03]

Existing federal law:
1) Establishes the Food, Drug, and Cosmetic Act (FDC Act) to regulate the safety of food, drugs, medical devices, and cosmetics. [Title 21, United States Code]

2) Defines a "medical device," under the FDC Act, in part, as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body, which does not achieve its primary intended purposes through chemical action within the body or upon being metabolized. [21 USC §321(h)]

This bill:

1) Requires an original equipment manufacturer (OEM) to make available, on fair and reasonable terms, any documentation, parts, and tools, including any updates to information or embedded software, needed for purposes of inspection, diagnosis, maintenance, or repair of powered medical equipment sold or used in this state. Specifies that an OEM is not required to make available a part if the part is no longer available to the OEM.

2) Requires an OEM to make available, on fair and reasonable terms, training courses and materials on the operation, inspection, diagnosis, maintenance, and repair of powered medical equipment sold or used in this state.

3) Requires an OEM to make the parts and information specified in 1) and 2) above available to an independent repair provider, as well as to the owner of powered medical equipment manufactured by, sold, or otherwise supplied by the OEM.

4) Requires an OEM, for equipment that contains an electronic security lock or other security-related function, to make available to the owner and to independent repair providers any special documentation, tools, and parts needed to disable the lock or function, and to reset it when disabled in the course of inspection, diagnosis, maintenance, or repair of the equipment. Permits the documentation, tools, and parts required to be made available by means of an appropriate secure system.

5) Requires an OEM, when it has made an express warranty with respect to powered medical equipment and the wholesale price of the equipment is $100 or more, to provide any parts, tools, and documentation needed to enable the repair of the equipment during the warranty period, at an equitable price and convenience of delivery and of suitable functionality, in light of all of the following considerations:

    a) The actual cost to the OEM to prepare and distribute the part, tool, or documentation, exclusive of any research and development costs incurred;
    b) The ability of owners and independent repair providers to afford the part, tool, or documentation; and,
    c) The means by which the part, tool, or documentation is distributed.

6) Specifies that this bill does not require an OEM to divulge a trade secret to an owner, or an independent service provider, except as necessary to provide documentation, parts, tools, and training courses and materials on fair and reasonable terms.

7) Prohibits any provision in this bill from being construed to alter the terms of any authorized repair agreement in force between an authorized repair provider and an OEM, including, but not limited to, the performance or provision of warranty or recall repair work by an authorized repair provider on behalf of an OEM, except that any provision that purports to waive, avoid, restrict, or limit the OEM's obligations to comply with this article are void and unenforceable.

8) Defines the following terms for purposes of this bill:

    a) "Authorized repair provider" means an individual or business who is unaffiliated with an original equipment manufacturer (OEM) and who has an arrangement with the OEM for a definite or indefinite period, under which the OEM grants to the individual or business

a license to use a trade name, service mark, or other proprietary identifier for the purposes of offering the services of inspection, diagnosis, maintenance, or repair of powered medical equipment under the name of the OEM, or other arrangement with the OEM to offer those services on behalf of the OEM. Specifies that an OEM who offers these services, and who does not have an arrangement with an unaffiliated individual or business, is considered an authorized repair provider;

b) "Powered medical equipment" or Equipment" is any powered device approved by the United States Food and Drug Administration (FDA) that is used in the treatment, monitoring, or diagnosis of a patient, and including assistive, adaptive, and rehabilitative devices;
c) "Documentation" is any manual, diagram, reporting output, service code description schematic, or other guidance or information used in effecting the services of inspection, diagnosis, maintenance, or repair of powered medical equipment;
d) "Embedded software" is any programmable instructions provided on firmware delivered with powered medical equipment, or with a part for that equipment, for purposes of equipment operation, including all relevant patches and fixes made by the manufacturer of the equipment or part for these purposes;
e) "Fair and reasonable terms for obtaining a part, tool, documentation, or training course and materials" means at costs and terms that are equivalent to the most favorable costs and terms under which an OEM offers the part, tool, documentation, or training course and materials to an authorized repair provider, including all of the following requirements:

    i) Accounting for any discount, rebate, convenient means of delivery, means of enabling fully restored and updated functionality, rights of use, or other incentive or preference the OEM offers to an authorized repair provider, or any additional cost, burden, or impediment the OEM imposes on an independent repair provider;
    ii) Not conditioned on, or imposing, a substantial obligation or restriction that is not reasonably necessary for enabling the owner or independent repair provider to engage in the diagnosis, maintenance, or repair of powered medical equipment made by, or on behalf of, the OEM; and,
    iii) Not conditioned on an arrangement described in the definition of "authorized repair provider" above.

f) "Fair and reasonable terms for documentation, including any relevant updates" means at no charge, except that, when the documentation is requested in physical printed form, permits a charge to be included for the reasonable actual costs of preparing and sending the copy;
g) "Fair and reasonable terms for software tools" means provided at no charge and without requiring authorization or internet access; without imposing impediments to access or use, in the course of affecting the diagnosis, maintenance, or repair and without impairing the efficient and cost-effective performance of the diagnosis, maintenance, or repair; and, that enables full functionality;
h) "Firmware" is a software program or set of instructions programmed on powered medical equipment, or on a part for that equipment, to allow the equipment or part to communicate within itself or with other computer hardware;
i) "Independent repair provider" is an individual or business operating in this state, who does not have an "authorized repair provider" arrangement with an OEM, and who is not affiliated with any individual or business who has such an arrangement, and who is engaged in the services of inspection, diagnosis, maintenance, or repair of powered

medical equipment. Specifies that with respect to an OEM, an individual or business who has such an arrangement with that OEM, or who is affiliated with an individual or business who has such an arrangement, is considered an independent repair provider for purposes of those instances in which it engages in the services of inspection, diagnosis, maintenance, or repair of powered medical equipment that is not manufactured by or sold under the name of that OEM;

j) "OEM" is a business engaged in the business of selling, leasing, or otherwise supplying new powered medical equipment manufactured by, or on behalf of, itself to any individual or business;

k) "Part" is any replacement part, either new or used, made available by an OEM for purposes of effecting the services of inspection, diagnosis, maintenance, or repair of powered medical equipment manufactured by, or on behalf of, sold, or otherwise supplied by the OEM;

l) "Tools" is any software program, hardware implement, or other apparatus used in inspection, diagnosis, maintenance, or repair of powered medical equipment, including software or other mechanisms that provision, program, or pair a new part, calibrate functionality, or perform any other function required to bring the product back to fully functional condition; and,

m) "Trade secret" means anything tangible or electronically stored or kept that constitutes, represents, evidences, or records intellectual property including secret or confidentially held designs, process, procedures, formulas, inventions or improvements, secrets of confidentially held scientific, technical, merchandising, production, financial, business, or management information, or anything within the definition specified federal law relating to trade secrets.

9) Provides that any person who knowingly violates any provisions of this bill, or who reasonably should have known that they violated any provision of this bill, to be liable for a civil penalty of up to $1,000 per day per piece of equipment for the first violation, $2,000 per day per piece of equipment for the second violation, and $5,000 per day per piece of equipment for the third and any subsequent violations. Requires these penalties to be assessed and recovered in a civil action brought by the California Attorney General or by any district attorney, county counsel, or city attorney.

10) Requires, if the action to enforce penalties under 7) above is brought by the Attorney General, one-half of the penalties collected to be paid to the treasurer of the county in which the judgment was entered, and one-half to the State Treasurer. If brought by a district attorney or county counsel, requires the entire amount of the penalties collected to be paid to the treasurer of the county in which the judgment was entered. If brought by a city attorney or city prosecutor, requires one-half of the penalties to be paid to the treasurer of the county and one-half to the city.

11) Exempts violations of this bill from existing penalty provisions in the California Sherman Food, Drug, and Cosmetic Act in favor of the penalty provisions specified in 9) above.

12) Permits penalties collected by the Attorney General under this bill to be expended by the Attorney General, upon appropriation by the Legislature, to enforce the provisions of this bill.

13) Requires the provisions of this bill to apply to equipment sold or in use on or after January 1, 2022.

FISCAL EFFECT: This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) *Author's statement.* According to the author, though the pandemic brought national attention to the Right to Repair, many critical devices have been left offline for days or weeks waiting for OEM–authorized repair technicians, while in-house experts and other third parties who can repair medical equipment immediately at a lower cost are locked out of the process. In addition to saving time and money, in 2018 the FDA found that: "we do not believe that a safety problem exists with the servicing, maintenance, and repair of medical devices by either third-party organizations or OEMs," and "the continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system." COVID-19 has shone a light on many inequities that simply do not need to exist. OEM's grip on repair can cost more money, take more time, and delay care. Allowing for independent repair will enable health care facilities to quickly service critical medical devices and equipment, preventing delays and improving patient care. This bill addresses this by requiring OEMs to provide parts, tools, documentation, and software updates needed for inspection, diagnosis, maintenance, or repair of medical devices to independent repairers and individual owners.

2) *Background on Right to Repair and U.S. PIRG survey of biomedical personnel.* According to an October 2020 article in the New York Times entitled *"Fix, or Toss? The 'Right to Repair' Movement Gains Ground,"* manufacturers of a wide range of products have made it increasingly difficult over the years to repair things, for instance by limiting availability of parts or by putting prohibitions on who gets to tinker with them. It affects not only game consoles or farm equipment, but cellphones, military gear, refrigerators, automobiles and even hospital ventilators. The article stated that a movement known as "Right to Repair" is starting to make progress in pushing for laws that prohibit restrictions like these, by pointing to a bill introduced in the last Congress by Senator Ron Wyden to block manufacturers' limits on medical devices (which did not advance and has not been reintroduced in this Congress), and other Right to Repair legislation getting introduced in more than 20 statehouses nationwide. So far, the most significant legislative advancement of the Right to Repair was an automotive Right to Repair bill passed in Massachusetts in 2012, which led to the automotive industry agreeing to make the same diagnostic tools available nationwide.

   The Digital Right to Repair Coalition (Coalition) was officially incorporated in 2013 by the Service Industry Association, the Association of Computer Dealers Inc, the National Association of Telecommunications Dealers, the Electronic Frontier Foundation, and iFixit.org, and has since expanded membership to include the U.S. Public Interest Research Group (PIRG), Consumers Union, and many other organizations. According to the Coalition, there are four underlying principles for the right to repair, including the jobs provided by businesses offering independent repair, reuse, or resale services; reducing electronic waster by extended the useful life of products; product value retention; and owners' rights.

   According to information provided by the author and sponsors, according to a survey of 222 biomedical repair technicians, clinical engineers, and health care technology management professionals done by U.S. PIRG in June 2020: 91.8% of respondents reported that they had been denied access to service information for "critical equipment" such as defibrillators,

ventilators, anesthesia machines, and imaging equipment; 30.4% reported equipment in their facilities could not be used due to restrictions on spare parts and service information; and, 68.5% of respondents said their hospital has had to "delay a patient procedure because they were waiting on a manufacturer service representative to fix a device." In a second survey of 129 biomedical personnel during the winter COVID-19 surge, 76% were denied access to parts or service materials for critical medical equipment as cases spiked, 80% had equipment they could not service because of restrictions to service keys, parts, or other materials, and 90% of respondents reported that the surge of COVID-19 cases had increased their need for medical Right to Repair.

3) *FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices (FDA Report).* The FDA Reauthorization Act of 2017 required the FDA to issue a report on the servicing of medical devices, which was published in May of 2018. In part, the FDA Report was required to present findings with respect to a proposed rule entitled "Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers: Request for Comments." Among other things, the FDA Report reviewed responses to the request for comments, summarized a public workshop that was held on the subject, and summarized key issues and on-going activities. Of particular relevance to this bill were the discussion of existing authority and regulations, a summary of evidence pertaining to medical device servicing, and the FDA Report's conclusions, each of which is summarized here:

   a) *Existing authorities and regulations*: Pursuant to the Medical Device Amendments to the FDC Act, enacted in 1976, the FDA is required to classify all devices into one of three regulatory control categories: Class I, Class II, or Class III, depending on the degree of regulation necessary to provide reasonable assurance of the safety and effectiveness of the device. Under the regulatory scheme, the safety and effectiveness of all medical devices is assured through general controls such as manufacturer registration and device listing, applicable good manufacturing practices, medical device reporting, reports of corrections and removals, unique device identification, and others. For Class II and III devices, there are special controls and premarket approval, respectively. Medical device reporting, which helps FDA assess significant adverse events and detect emerging problems associated with the use of medical devices, apply to manufacturers, importers of devices manufactured outside of the United States, and user facilities. There is no requirement for third-party repair organizations to report. Under medical device reporting requirements, manufacturers are required to report to the FDA when their devices may have caused or contributed to a death or serious injury, or their device has malfunctioned and would be likely to cause or contribute to death or serious injury. Device user facilities, on the other hand, are required to report to the FDA and to the manufacturer when a device may have caused or contributed to a death, and to report to the manufacturer only when a device may have caused or contributed to a serious injury. A "device user facility" is defined as a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility that is not a physician's office. The FDA Report noted that most device reports "do not include detailed information concerning the servicing history of the medical device, such as who serviced the device and what service was done, when the device was serviced, how often the device was serviced, what parts were replaced or repaired, and what testing was completed after the device was serviced."

FDA states that while it has generally not enforced the FDA Act requirements with respect to servicing activities, it has consistently interpreted its provisions to apply or potentially apply to servicing activities, and states that it is proposing to add general requirements for the maintenance of servicing records, and that servicing controls will apply to servicing conducted or controlled by a manufacturer. However, the FDA Report states that "In 1996, FDA ultimately excluded servicers and refurbishers, as those terms relate to entities outside the control of the OEMs from the final quality system regulation." In doing so, the FDA explained that although "it believes that persons who perform such functions meet the definition of manufacturer," the nature of servicing involved a "number of competitive and other issues" that would be worked through in a separate rulemaking." No separate rulemaking was undertaken, and therefore independent servicers outside of the control of the OEM are not regulated by FDA. Beyond servicing, any person who "processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use" meets the definition of a remanufacturer, and is subject to regulation by FDA.

The FDA Report also pointed to the involvement of the Centers for Medicare and Medicaid Services (CMS) in the regulation of medical devices through conditions of participation for health facilities receiving federal payments. In 2013, CMS updated its guidelines for hospital equipment maintenance requirements. In general, hospital are required to maintain equipment (which includes medical devices) in accordance with the OEM's recommendations. However, hospitals are permitted to adopt an "Alternate Equipment Management" program that allows the hospital to adjust its maintenance activities from what is recommended by the manufacturer based on a risk-based assessment by qualified personnel. The determination to perform medical equipment maintenance without following OEM recommendations must be made by qualified personnel, such as a clinical or biomedical technician or engineer. Hospitals are required to maintain documentation, including the date when maintenance activities were performed, and documentation of any equipment failures. Survey procedures for ensuring compliance include determining if the hospital has documentation of the qualifications of hospital personnel responsible for the Alternative Equipment Management program, as well as for those performing maintenance, such as training certificates, certifications, degrees, etc., and the surveyor is required to determine if the hospital is able to demonstrate how it assures contractors use qualified personnel.

b) *Summary of evidence pertaining to medical device servicing*. First, the FDA Report estimated the number of entities performing medical device servicing in the United States at between 16,520 and 20,830 (this did not include OEMs). The FDA conducted a literature review to assess what peer-reviewed published evidence was available on the quality, safety, and effectiveness of medical device servicing, which was limited to English language articles published on or after January 1, 2008. While the initial search using a number of key search terms identified 502 articles, upon further review, there were no studies with sufficient, high-quality data from which conclusions could be drawn about the safety and effectiveness of medical device servicing. The ECRI Institute submitted a summary of their research and analysis to FDA, which looked at the FDA's medical device report database from 2006-2015 (2,114,303 records), ECRI Institutes Health Device Alerts Tracker Database from 2006-2015 (528 records), and ECRI Institutes confidential contracted accident investigations from 2006-2015 (692 investigations). After reviewing and excluding reports for a variety of reasons (i.e., they

were for disposable or single use devices, manufacturer or operator errors, or no maintenance performed at all), ECRI Institute identified only 86 medical device reports (0.0004% of device reports analyzed), four ECRI Health Devices Alerts Tracker reports (0.8%), and six ECRI Institute contracted accident investigations (0.9%). ECRI Institute therefore concluded that they do not believe a safety problem exists with the servicing, maintenance, and repair of medical devices by either third party organizations or OEMs.

The FDA also evaluated its medical device reports, going back to 1992 and including reports submitted as of June 30, 2017. There were 4,301 reports that explicitly stated that a device was repaired, replaced, or maintained by a third party servicer, and that of these, there were 40 deaths, 294 serious injuries, 3,791 malfunction reports, and 176 classified as "other." Most of these reports (4,240) came from OEMS, with 25 from user facilities, 16 from distributors, and 20 from voluntary sources. Of the death reports, only three contained sufficient information to definitively conclude that servicing caused or contributed to the death: two field service engineers were killed while servicing a Computed Tomography scanner and an MRI scanner, respectively, and a death occurred after a patient lift rail was reinstalled incorrectly. A fourth death was due to the malfunction of a remanufactured imaging system that lacked FDA clearance or approval, when the camera fell on and killed the patient. Due to the limited information contained in the 334 device reports of death or serious injury, FDA stated it was not able to establish a conclusive relationship between third party servicing and subsequent adverse events.

Finally, the FDA looked at complaints received since 2009, and identified a total of 68 potentially relevant complaints. Of those, 28 were related to device remanufacturing, including the replacement of parts not consistent with OEM specification. The remaining 40 complaints alleged inadequate serving, ranging from customers being charged for repair services, OEMs not providing service manuals, and OEMs not providing critical replacement parts, to poor technician training, knowingly falsifying service records, and repairs using broken replacement parts. Of the 40 complaints, 18 alleged that the inadequate servicing could lead to a serious adverse event, and only one reported that adverse events occurred. In that complaint, two patients were injured due to an independent repair organization repairing an infusion pump with allegedly defective parts. In total, the FDA concluded that these complaints demonstrate that there may be isolated instances of poor quality servicing by OEMs or third party entities.

c) *Conclusions*. The FDA Report concludes as follows: We believe the currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern relating to servicing of medical devices, including by third party servicers, that would justify imposing additional/different burdensome regulatory requirements at this time. Although we do not believe that additional, formal regulatory action is warranted, based on the available information and findings, we intend to pursue the following actions:

i) Promote the adoption of Quality Management Principles;
ii) Clarify the difference between servicing and remanufacturing;
iii) Strengthen cybersecurity practices associated with servicing of medical devices; and,
iv) Foster evidence development to assess the quality, safety and effectiveness of medical device servicing.

4) *Double referral.* This bill is double referred. Should it pass out of this committee, it will be referred to the Senate Committee on Judiciary.

5) *Prior legislation.* AB 1163 (Eggman of 2019) would have require specified electronics and appliance manufacturers to make available sufficient service literature and functional parts to owners of the equipment or products and service dealers to effect the repair of a product, as specified. *AB 1163 was not heard in the Assembly Committee on Privacy and Consumer Protection.*

   AB 2110 (Eggman of 2018) would have established the Right to Repair Act to require the OEM to provide independent repair providers and owners of the equipment certain parts, tools, and information, including diagnostic and repair information, for purposes of providing a fair marketplace for the repair of that equipment. Medical devices and electronic products manufactured exclusively for use in a health care setting were specifically exempted from the provisions of this bill. *AB 2110 was not heard in the Assembly Committee on Privacy and Consumer Protection.*

6) *Support*. This bill is cosponsored by CALPIRG, the American College of Clinical Engineering, and iFixit. The sponsors right that hospital repair technicians, known as biomeds, often have difficulty getting access to the repair information and parts they need from OEMs to keep equipment up and running. Sponsors state that hospitals cannot afford to deal with OEM repair restrictions or wait for OEM-authorized technicians to show up on site. Sponsors state that this problem is exacerbated for rural hospitals, who have reported that they have had to wait weeks and even a month for a manufacturer representative to travel to their hospital and service broken equipment. Sponsors also stated that OEMs charge much more for repair, increasing healthcare costs. According to the sponsors, when performed under an OEM contract, service can cost as much as 10 to 15% of the device's original cost, compared to 5 to 8% for an independent service organization or 3 to 4% for hospital-employed biomeds. Given the cost of some of these machines, these difference can lead to a much high repair bill. Sponsors cited an example of a repair needing a replacement part costing $80, but the biomed being told by the OEM that their repair technicians needed to come in and make the repair for a cost of $4,000.

   The California Hospital Association (CHA), along with the hospitals of Cedars Sinai, French Hospital Medical Center, and Washington Hospital Healthcare System, support this bill. CHA states in support that if OEMs were to provide information and repair parts to hospitals' teams to make repairs, delays could be avoided, which would help make potentially life-saving medical technology more available to patients.

7) *Opposition.* A coalition of opponents, including AdvaMed, the Medical Imaging and Technology Alliance, the Security Industry Association, TechNet, and the Telecommunications Industry Association, among others, submitted a coalition opposition letter. The opposition states that this would mandate OEMs provide independent repair providers with diagnostic and repair information, software, tools, and parts, but without requiring any of the critical consumer protections afforded by authorized repair networks, such as training and competency certification, putting at risk protections manufacturers have built in for consumer data privacy and security. Opponents argue this bill harms consumer security, harms consumer safety, mandates the disclosure of protected proprietary information, and fails to account for advancements in sustainability by electronic product

manufacturers. Regarding consumer security, opponents state that this legislation has the potential to weak the privacy and security features of various electronic products, and that in an era of sophisticated cyberattacks, we should not make it easier for criminal to hack security provisions by mandating all manufacturers provide a "how to" manual for any product to anyone who asks. Regarding consumer safety, manufacturers want to ensure their products are serviced by professionals who understand the intricacies of their products and have spent time procuring the knowledge necessary to safely repair them and return them to consumers. Opponents state that OEM's authorized networks of repair facilities guarantee that repairs meet OEM performance and safety standards. Regarding the disclosure of protected proprietary information, opponents state that on-board software, or firmware, is key to the functioning and operation of the hardware it is embedded in, and firmware helps protect against unauthorized access to other software and applications. According to the opponents, making repairs to hardware components may require the circumvention of digital rights management and leave the software in an unprotected state, harming the copyright owners of the software. Opponents further state that firmware controls many other product functions, and opening it up for repair purposes exposes other more sensitive functions, such as security features, to potential tampering. Finally, opponents argue that this bill is partly based on an inaccurate assumption that the bill will aid in the reduction of electronic waste in California, yet opponents point to a recent study showing that e-waste generation peaked in 2015 and is in a period of extended decline. Opponents state that repair and reuse are important elements of OEMs sustainability efforts.

8) *Policy comments.*

a) *Hospitals versus all independent repair organizations*. Compared to household appliances and consumer electronics, medical devices are highly regulated, with the most advanced medical advices requiring premarket approval from the FDA, and all medical devices subject to adverse event reporting. However, this regulation does not extend to repair providers outside of the control of manufacturer: unless a repair provider meets the definition of a "remanufacturer" by changing the performance, specifications, or intended use of a medical device (which would then essentially trigger regulation as a manufacturer), independent repair providers are not subject to mandatory adverse event reporting, and will not be subject to direct regulation by the FDA and any quality and safety standards associated with maintenance, servicing and repair that FDA enforces. However, as described in comment 3) a) above, there are certain requirements that apply to the owners, or "user facilities," of medical devices. User facilities such as hospitals, nursing homes and certain types of outpatient treatment facilities are required to report medical device adverse events that result in a death to the FDA and the OEM, and to the OEM for serious injury adverse events. Additionally, for hospitals in particular, CMS's conditions of participation impose requirements on hospitals pertaining to the maintenance and servicing of medical devices, including ensuring that their repair technicians are qualified, and that maintenance and service information is documented. The Committee may wish to consider whether it is appropriate to limit the application of this bill to regulated environments such as hospitals that have requirements to ensure the safe maintenance and repair of medical devices.

b) *Should there be any limitation on the scope of access to software and security features?* Among the items that an OEM is required to provide are "any updates to information or embedded software, needed for purposes of inspection, diagnosis, maintenance, or repair" and "any special document, tools, and parts needed" to disable "an electronic security

lock or other security-related function." Additionally, under this bill OEMs are prohibited from imposing impediments to access or use, and are required to enable full functionality. The intent behind these provisions is to ensure repair technicians are able to make the repair, as many electronic devices have security features that are required to be disabled and then reset in order to repair. Opponents argue that this language is sufficiently broad as to risk patient confidentiality. The author may wish to explore whether this language should be narrowed to limit the requirement to provide access to software and security features to only that necessary to effect servicing and repair.

SUPPORT AND OPPOSITION:

Support:
American College of Clinical Engineering (co-sponsor)
CALPIRG (co-sponsor)
IFIXIT (co-sponsor)
Association of Medical Device Service Organizations
Association of Regional Center Agencies
California Hospital Association
Cedars-Sinai
Dignity Health
EP Radiological Services, Inc.
French Hospital Medical Center
MultiMedical Systems
National Stewardship Action Council
Renovo Solutions
Sodexo Clinical Technology Management
Sutter Health
Washington Hospital Healthcare System

Oppose:
Advanced Medical Technology Association
Air Conditioning, Heating and Refrigeration Institute
Association of Home Appliance Manufacturers
Consumer Technology Association
CTIA – The Wireless Association
Entertainment Software Association
Information Technology Industry Council
Internet Coalition
Medical Imaging & Technology Alliance
National Electronic Manufacturers Association
NetChoice
PRBA – The Rechargeable Battery Association
Repair Done Right
Security Industry Association
State Privacy and Security Coalition, Inc.
TechNet
Telecommunications Industry Association
The Toy Association

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