Chapter 521: Overexposed: Radiology Errors Lead to Harm from CT Scans

Christopher Braniff

Code Sections Affected
SB 1237 (Padilla); 2010 STAT. Ch 521.

I. INTRODUCTION

Fearing a potential stroke, Michael Heuser visited Cedars-Sinai Medical Center in Los Angeles. His doctor ordered a computed tomography (CT) examination, a common tool used to diagnose potential stroke victims. As part of the examination, doctors injected Michael with an iodine solution while a series of X-rays created a detailed image of how blood flowed to Michael’s brain. Not long after this examination, Michael began experiencing new symptoms: reddened skin and sudden hair loss. A subsequent investigation revealed that each CT scan had mistakenly administered eight times the intended dosage of radiation, causing Michael to receive the equivalent radiation of approximately 50,000 chest X-rays.

Investigators traced the problem back to an error made when the hospital reconfigured their CT examination machine to improve image quality eighteen months earlier. Because every scan performed by an examination contained its own set of computerized instructions, the error made by Cedars-Sinai staff was repeated a number of times. Thus, from February 2008 until October 2009, 206...
patients received an overdose of radiation.\textsuperscript{9} Other hospitals around the country have also reported radiation overdoses due to their CT scanners.\textsuperscript{10}

Chapter 521 addresses the problem of accidental radiation overdose by changing requirements in the Health and Safety Code relating to CT examinations.

II. LEGAL BACKGROUND

Medical imaging is a common tool in the diagnosis of many types of diseases.\textsuperscript{11} Greater use of medical imaging has led to an increase in both the amount of radiation patients are exposed to and the errors associated with administering such examinations.\textsuperscript{12}

A. Radiation from Medical Imaging is on the Rise

Between 1981 and 2006, the average annual effective dose of ionizing radiation received by Americans has nearly doubled.\textsuperscript{13} Ionizing radiation can damage DNA and cause cancer.\textsuperscript{14} This increase is due almost entirely to the increase of medical imaging procedures.\textsuperscript{15} The average amount of radiation Americans receive from medical imaging procedures is seven times greater than it was in 1980\textsuperscript{16} and accounts for forty-eight percent of all exposure to ionizing radiation.\textsuperscript{17}

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\textsuperscript{9} Zarembo, Hospital Error Leads to 206 Radiation Overdoses, \textit{supra} note 5. By May 2010, there were more than 260 confirmed cases of over-radiation. Zarembo, Senate Approves Bill on CT Scans, \textit{supra} note 1.


\textsuperscript{12} See id. (explaining that the use of medical imaging has increased the exposure of radiation among the U.S. population).

\textsuperscript{13} DOUGLAS C. GIANCOLI, \textit{PHYSICS FOR SCIENTISTS AND ENGINEERS WITH MODERN PHYSICS} 1100 (3d ed. 2000). The average annual effective dose of ionizing radiation is the amount of ionizing radiation an average American is exposed to over the course of a year. \textit{Id.} Ionizing radiation is radiation that can ionize atoms or molecules and thus cause significant damage to biological tissue. \textit{Id.}

\textsuperscript{14} Wall, \textit{supra} note 11, at 136 (noting an increase by a factor of 1.7).


\textsuperscript{16} Wall, \textit{supra} note 11, at 136.


\textsuperscript{18} Wall, \textit{supra} note 11, at 136.
The single largest contributor of medical imaging radiation is the CT examination, accounting for half of all medical exposures. A single CT examination may result in a patient receiving the equivalent amount of radiation as 100 chest x-rays, depending on the type of scan administered. In 2006, sixty-two million Americans received CT examinations, which have increased ten percent annually over the past two decades.

B. Errors Leading to Overdose of Radiation

According to the U.S. Food and Drug Administration (FDA), medical imaging should only expose a patient to the minimum radiation “necessary to produce a high-quality image.” Software flaws, faulty programming, poor safety procedures or inadequate staffing . . . can all lead to accidental overdoses. Newer CT machines might display the radiation dosage administered, but most devices do not warn when a radiation dose exceeds safe levels. Although the CT machines at Cedars-Sinai hospital displayed the dosage of radiation administered on a computer screen during each examination, operators failed to take notice. Because the hospital failed to save record of the radiation dosage, the completed examination contained no record that patients had been overdosed.

Determining how often radiotherapy accidents occur is difficult. Accidents often go unreported. Years may pass after a patient is exposed to an overdose of radiation before cancer or organ damage becomes apparent. One study estimated that as many as 29,000 future cancers could be related to CT examinations performed in the United States in 2007.

In October 2009, the FDA issued a warning against overexposure to radiation from CT scans and recommended that medical service providers carefully monitor the dosage of radiation received during an examination.
III. CHAPTER 521

Starting July 1, 2012, Chapter 521 requires hospitals and clinics to measure and record the dosage of radiation received by patients during CT scans.\textsuperscript{32} Hospitals and clinics must electronically archive each dosage and include it in a radiology report.\textsuperscript{33} In addition, this legislation requires a medical physicist to annually verify that the dosage displayed by CT machines is within twenty percent of the true measured value.\textsuperscript{34}

Chapter 521 further requires hospitals and clinics to notify the patient, the referring physician, and the State Department of Public Health when certain errors have occurred.\textsuperscript{35} Such errors include when an equipment defect or failure has causes a CT scan to be repeated, when the wrong patient or body part has been irradiated, and when the administered dose exceeds established protocols.\textsuperscript{36}

Beginning July 1, 2013, Chapter 521 also requires that “facilities that furnish CT X-Ray services shall be accredited by an organization that is approved by the federal Centers for Medicare and Medicaid Services, an accrediting agency approved by the Medical Board of California, or the State Department of Public Health.”\textsuperscript{37}

IV. ANALYSIS

A. Improving the Quality of Care through Accreditation Standards

Chapter 521 will likely reduce the number of accidental overdoses of radiation by recording the amount of radiation received by patients during CT examinations. The Consumer Federation of California, a supporter of the legislation, noted that catching overdose errors from CT examinations was nearly impossible prior to Chapter 521 because such errors were difficult to detect.\textsuperscript{38} The radiologists who administered Michael Heuser’s CT examination, for example,

\textsuperscript{32}. CAL. GOV’T CODE § 115111(a) (enacted by Chapter 521). Chapter 521 provides that “dose of radiation shall be defined as one of the following: (1) The computer topography index volume . . . and dose length product . . . , as defined by the International Electromechanical Commission . . . and recognized by the federal Food and Drug Administration . . . . [Or] (2) The dose unit as recommended by the American Association of Physicists in Medicine.” \textit{Id.} § 115111(f)(1)-(2) (enacted by Chapter 521).

\textsuperscript{33}. Id. § 115111(b) (enacted by Chapter 521).

\textsuperscript{34}. Id. § 115111(c) (enacted by Chapter 521).

\textsuperscript{35}. Id. § 115113(a)-(b) (enacted by Chapter 521).

\textsuperscript{36}. See id. § 115111(a)(1)-(6) (enacted by Chapter 521) (listing circumstances when reporting is mandated).

\textsuperscript{37}. Id. § 115112 (enacted by Chapter 521).

might have caught the error if he or she had recorded the dosage of radiation administered in the radiology report.\textsuperscript{39}

By requiring hospitals that perform CT examinations to be accredited by one of several organizations,\textsuperscript{40} Chapter 521 will bring oversight of such imaging in line with national trends.\textsuperscript{41} Current federal law requires healthcare facilities seeking reimbursement for Medicare patients to meet established quality and accreditation standards.\textsuperscript{42} Physicians and scholars have noted that the accreditation and measurement required under federal law has been successful at improving the quality of patient care.\textsuperscript{43} Because Chapter 521 adopts these same accreditation standards, patient health is likely to improve.\textsuperscript{44}

\textbf{B. Changes to Machine Manufacture May Better Prevent Accidental Overdoses}

Some opponents of Chapter 521 fear that it does not go far enough to fix the problem.\textsuperscript{45} For example, Dr. Thomas Dehn, the chief medical officer for National Imaging Associates Incorporated, a private healthcare plan manager, suggests that the fixes required by Chapter 521 cannot correct for human error.\textsuperscript{46} Because technicians are already trained to observe the dosage levels administered during a CT examination, requiring the dosage to be recorded and included in the radiology report will do little to prevent negligent technicians from doing harm.\textsuperscript{47}

Others, such as Dr. Jeffery Shuren, director of the Center for Devices and Radiological Health, suggests that the greatest cause of accidental overdoses of radiation is the machines themselves.\textsuperscript{48} In a letter to CT machine manufacturers, Dr. Shuren cites software problems as the greatest cause of errors.\textsuperscript{49} Such a software problem, according to a statement by Cedars-Sinai, contributed to the

\begin{itemize}
\item \textsuperscript{39} See Zarembo, \textit{Hospital Error in Plain Sight}, supra note 25 ("CT technicians are not the only medical personnel who might have caught the error at Cedars-Sinai. Radiologists might have seen the numbers—but only if the hospital had elected to save the dosage data with the images.").
\item \textsuperscript{40} CAL. GOV’T CODE § 115112 (enacted by Chapter 521).
\item \textsuperscript{41} See Walt Bogdanich, \textit{F.D.A. to Increase Oversight of Medical Radiation}, N.Y. TIMES, Jan. 24, 2010, at A1 (noting the growing movement to make diagnostic medical radiation safer).
\item \textsuperscript{42} See Medicare Modernization Act, 42 U.S.C. § 1395cc-3(d) (2006).
\item \textsuperscript{43} Mark R. Chassin et al., \textit{Accountability Measures—Using Measurement to Promote Quality Improvement}, NEW ENG. J. MED., June 23, 2010, at 2.
\item \textsuperscript{44} See CAL. GOV’T CODE § 115112 (enacted by Chapter 521) (detailing the accreditation standards); Chassin et al., supra note 43, at 2 (noting that standardized data organization can improve the quality of healthcare).
\item \textsuperscript{45} See Zarembo, \textit{Hospital Error in Plain Sight}, supra note 25 (noting improvements that could still be made).
\item \textsuperscript{46} See id. (noting that Dehn suggests a “radiation threshold [on CT machines] that cannot be exceed without a person acknowledging that the dosage is intentional”).
\item \textsuperscript{47} See id. (explaining that a failure by CT technicians to notice dosage levels during scans was under review).
\item \textsuperscript{49} Id.
\end{itemize}
accidental overdose of radiation received by Michael Hauser and others.\textsuperscript{50} The software used by Cedars-Sinai had a feature that technicians believed would lower the dosage of radiation but, in fact, significantly raised it.\textsuperscript{51} Both Dr. Shuren and Dr. Dehn recommend that the best way to prevent accidental overdoses may be to design CT equipment incapable of exceeding a certain safe level of radiation.\textsuperscript{52}

C. Litigation Not Likely to Increase

Although overdoses from CT examinations will be documented under Chapter 521, such documentation is not likely to lead to a significant increase in lawsuits against healthcare providers.\textsuperscript{53} Radiation injuries seldom result in lawsuits because such injuries are hard to detect.\textsuperscript{54} Although overdosed patients face an increased risk of brain tumors, the risk is still small.\textsuperscript{55} In cases where cancer does develop, tumors will not manifest until decades after the initial overdose of radiation.\textsuperscript{56} This makes it difficult to prove causation in a lawsuit.\textsuperscript{57} For this reason, many acknowledge that the class-action lawsuit filed on behalf of Cedars-Sinai patients is unlikely to be successful.\textsuperscript{58}

V. CONCLUSION

Prior to Chapter 521, hospitals and clinics were not required to measure and record the dosage of radiation received during a CT examination, making any accidental overdose of radiation difficult to catch.\textsuperscript{59} By requiring healthcare facilities to measure and record this dosage of radiation, Chapter 521 will likely reduce the incidents of accidental overdose and lead to greater patient safety.\textsuperscript{60} By requiring hospitals and clinics to immediately notify patients, their doctors, and the State Department of Public Health of errors in administering CT

\textsuperscript{50} Walt Bogdanich, After Stroke Scans, Patients Face Serious Health Risks, N.Y. TIMES, July 31, 2010, at A1.
\textsuperscript{51} Id.
\textsuperscript{52} Bogdanich, F.D.A. Toughens Process for Radiation Equipment, supra note 48; Zarembo, Hospital Error in Plain Sight, supra note 25.
\textsuperscript{53} Bogdanich, Radiation Offers New Cures, supra note 17.
\textsuperscript{54} Id. (noting that it is difficult to identify injuries from radiation because “[o]rgan damage and radiation-induced cancer might not surface for years or decades . . .”).
\textsuperscript{56} Id.
\textsuperscript{57} Id.
\textsuperscript{58} Id.
\textsuperscript{59} Zarembo, Hospital Error in Plain Sight, supra note 25.
\textsuperscript{60} See generally Bogdanich, F.D.A. to Increase Oversight, supra note 41 (noting the hope that regulation of medical imaging will lead to a decrease in accidental exposure to radiation).
examinations, Chapter 521 will likely prevent the type of repetitive errors seen at Cedars-Sinai hospital that harmed Michael Heuser.\textsuperscript{61}
Chapter 19: Requiring a Carbon Monoxide Detector in Every Home

Will Melehani

Code Sections Affected
Civil Code §§ 1102.6, 1102.6d (amended); Health and Safety Code §§ 13260-13263, 17926-17926.1, 17926.2 (new).
SB 183 (Lowenthal); 2010 STAT. Ch. 19.

I. INTRODUCTION

New Year’s celebrations were cut short for one family in Novato, California, when nausea and dizziness prompted the family of five, including an infant and grandmother, to visit a hospital emergency room.\(^1\) The family’s symptoms led local firefighters to suspect carbon monoxide as the culprit.\(^2\) After investigating their home, firefighters discovered the deadly gas had reached a concentration capable of causing imminent death.\(^3\) The source of the lethal gas appeared to be a malfunctioning wall heater.\(^4\)

While this particular Novato family fully recovered, many other families are not so lucky.\(^5\) The Centers for Disease Control and Prevention estimate that each year carbon monoxide poisoning is responsible for 15,200 injuries and 480 deaths nationally.\(^6\) They also estimate that at least one Californian dies from carbon monoxide poisoning each year.\(^7\)

Carbon monoxide is invisible, odorless, and can be emitted from vehicles, furnaces, and a wide variety of appliances, threatening nearly all residential buildings.\(^8\) Chapter 19 requires at-risk residences to have working carbon

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\(^2\) Id.
\(^3\) See id. (stating that the house contained carbon monoxide levels “well over” 400 parts per million, at which death can occur within three to five hours”).
\(^4\) Id.
\(^5\) See id. (stating the family made a full recovery).
\(^8\) See Centers for Disease Control and Prevention, Unintentional Non-Fire-Related Carbon Monoxide Exposures, supra note 6 (describing the properties and sources of carbon monoxide).
monoxide detectors and sets up a process for approving detectors for sale within the state of California.\(^9\)

II. LEGAL BACKGROUND

Establishing a building standard in California requires a unique regulatory process.\(^10\) Some standards, such as the requirement for smoke detectors, have avoided this process through statutory mandates.\(^11\)

A. Building Standards

Building standards in California must be established in accordance with the California Building Standards Law.\(^12\) This law created the California Building Standards Commission (CBSC) and authorized them to amend the model building codes used in California in accordance with proposals of state agencies, such as the Department of Housing and Community Development (HCD).\(^13\) While the HCD makes proposals regarding residential buildings,\(^14\) the CBSC has not adopted any of the proposed regulations requiring carbon monoxide detectors.\(^15\) Because newly adopted building standards do not apply to existing structures, Chapter 19 was passed to apply a standard to existing structures.\(^16\)

B. Smoke Detectors

Certain statutorily mandated building standards—such as the California residential smoke detector requirement—have been established without going through the CBSC’s regulation-adopting process.\(^17\) California’s requirement for residential smoke detectors mandates that smoke alarms be placed in every new building, as well as in older buildings that undergo alterations costing $1,000 or

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9. See CAL. HEALTH & SAFETY CODE § 17926(a)(1)-(2) (enacted by Chapter 19) (requiring carbon monoxide detectors be installed in covered single family dwellings by July 1, 2011, and in all other covered dwellings by January 1, 2013); id. § 13263(a) (enacted by Chapter 19) (requiring the State Fire Marshall to certify and list approved devices).
11. See id. § 13113.7 (requiring working smoke detectors in dwellings).
12. Id. § 18901.
13. Id. § 18930.
14. See id. § 17921 (stating the HCD shall propose amendments to building regulations concerning “hotels, motels, lodging houses, apartment houses, and dwellings, and buildings and structures accessory thereto” to the CBSC).
16. See CAL. HEALTH & SAFETY CODE § 18909(a) (stating that building standards apply only to new construction, repairs, alterations, etc.).
17. See id. § 13113.7 (requiring dwellings to have working smoke detectors).
more. The owner of the dwelling has a duty to purchase, install, and maintain its smoke detectors. However, the law excuses the owner’s duty to repair a dysfunctional smoke detector if he or she lacked notice of the problem.

Violations of this law are punishable by a fine of two hundred dollars. For single family dwellings, the law specifically states that no transfer of title will be invalidated by a failure to comply with the smoke detector requirement, and that any damages for a failure to comply will be limited to actual damages no more than one hundred dollars. Using these smoke detector laws as a framework, Chapter 19 establishes new rules requiring carbon monoxide detectors.

III. CHAPTER 19

Chapter 19 enacts the Carbon Monoxide Poisoning Prevention Act of 2010, establishing new housing and manufacturing requirements concerning carbon monoxide detectors. It requires the State Fire Marshall to develop a certification process for carbon monoxide detectors and to maintain a list of certified detectors. Approved detectors must satisfy several criteria, such as passing performance tests set by nationally-recognized standards and creating an audible alarm that is distinct from that of a smoke detector. Manufacturers are prohibited from selling any carbon monoxide detectors in California that are not on the State Fire Marshall’s certified list.

Chapter 19 also requires that nearly all dwellings intended for human habitation have carbon monoxide detectors installed by specific deadlines. This portion of Chapter 19 largely mirrors the law concerning smoke detectors.

18. Id. § 13113.7(a)(1)-(2).
19. Id. § 13113.7(c), (e).
20. Id. § 13113.7(e).
21. Id. § 13113.7(f).
22. Id. § 13113.8(g).
23. See id. (stating that the exclusive remedy for a failure to comply is actual damages of no more than $100, as well as court and attorney fees).
24. See id. §§ 13113.7, 13113.8 (applying only to smoke detectors, not carbon monoxide detectors).
25. Id. § 13260 (enacted by Chapter 19).
26. Id. § 13263(a)(1) (enacted by Chapter 19).
27. See id. § 13262(a)(4) (enacted by Chapter 19) (requiring carbon monoxide detectors to meet the requirements of “the American National Standards Institute (ANSI) and Underwriters Laboratories Inc. (UL) as set forth in either ANSI/UL 2034 or ANSI/UL 2075, or successor standards, by a nationally recognized testing laboratory listed in the directory of approved testing laboratories established by the Building Materials Listing Program of the Fire Engineering Division of the Office of the State Fire Marshal of the Department of Forestry and Fire Protection”).
28. See id. § 13262(a)(3)(C) (enacted by Chapter 19) (requiring carbon monoxide detectors that are also smoke detectors to have distinct alarms).
29. Id. § 13263(b) (enacted by Chapter 19).
30. See id. § 17926(a)(1)-(2) (enacted by Chapter 19) (requiring carbon monoxide detectors be installed in covered single family dwellings by July 1, 2011, and in all other covered dwellings by January 1, 2013).
31. Compare id. §17926 (enacted by Chapter 19) (requiring carbon monoxide detectors), with id. §§
Buildings that meet certain risk-related criteria are subject to the requirements in Chapter 19, although some buildings are exempt. Failing to install a carbon monoxide detector by the deadline, or failing to maintain the detector thereafter, will result in a thirty-day notice plus a fine of not more than two hundred dollars.

Chapter 19 charges the owners of covered dwellings with the duty to install, repair and maintain the carbon monoxide detector in compliance with building standards or the device’s instructions. Tenants have a duty to inform the owners of any suspected deficiencies in the carbon monoxide detector. An owner cannot be held in violation for a deficient carbon monoxide detector when he or she has not received notice of the defect.

Finally, Chapter 19 allows the HCD to temporarily suspend the enforcement of the Carbon Monoxide Poisoning Prevention Act of 2010 if there is an insufficient supply of approved carbon monoxide detectors. Lastly, in the event the CBSC adopts new building standards that would require more carbon monoxide detectors in a dwelling, owners would only be required to install new devices if the dwelling is altered or repaired at a cost of over $1,000.

VI. ANALYSIS

Chapter 19 has several benefits, the foremost being that it will reduce the amount of deaths caused by carbon monoxide. Concerns exist, however, regarding Chapter 19’s effectiveness.

A. Benefits of the Carbon Monoxide Poisoning Prevention Act of 2010

Normally, in order to create a building standard that would require carbon monoxide detectors in dwellings, the HCD would have had to propose an
amendment to one of the model codes, which the CBSC would then have to approve. The standard process for adopting new building regulations, however, fails to apply new standards to existing buildings. Chapter 19 prevents carbon monoxide poisoning sooner by requiring detectors in existing buildings, in addition to those required in newly-built buildings.

Carbon monoxide poisoning presents a threat to public health and welfare that affects approximately 15,000 people each year. By requiring detectors in existing buildings, Chapter 19 should vastly reduce the number of injuries caused by carbon monoxide. While carbon monoxide does pose a threat to individuals who are awake and alert, victims of carbon monoxide poisoning are often times asleep, intoxicated, or both. Additionally, victims of carbon monoxide poisoning are likely to be near or inside running cars or other loud machinery. For these reasons, an audible alarm is needed to warn potential victims, and such an alarm will likely prevent many potential injuries. Public safety and rescue personnel agree that Chapter 19 will effectively prevent carbon monoxide related injuries.

In addition, by authorizing the State Fire Marshall to test and certify carbon monoxide detectors, Chapter 19 will likely improve the quality of detectors and protect the public from detectors that remain prone to producing false alarms.

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41. See CAL. HEALTH & SAFETY CODE § 18930 (stating that state agencies are required to submit building standards to the CBSC for approval).
42. See id. § 18909(a) (stating that building standards apply only to new construction, repairs, alterations, etc.).
43. See id. § 17926(a)(1)-(2) (enacted by Chapter 19) (requiring carbon monoxide detectors be installed in covered single family dwellings by July 1, 2011, and in all other covered dwellings by January 1, 2013).
44. Centers for Disease Control and Prevention, Unintentional Non-Fire-Related Carbon Monoxide Exposures, supra note 6.
45. See id. (stating the author’s arguments that carbon monoxide detectors in homes would prevent carbon monoxide related injuries);
see also CAL. HEALTH & SAFETY CODE § 13260(e) (enacted by Chapter 19) (stating the legislative finding that equipping every home with a carbon monoxide detector would cut accident related costs by 93 percent).
46. See Yoon et al., supra note 39, at 686 (stating that 42% of the sample victims had a BAC over .01, and only 51% of the victims were awake when they died in their residences).
47. See id. (stating that 68 out of the 136 tested died in or around motor vehicles).
48. See id. at 687 (stating that an effective alarm would need to be audible to a sleeping person or person near a car or loud machinery).
50. See CAL. HEALTH & SAFETY CODE § 13263(a)(1) (enacted by Chapter 19) (requiring the certification of carbon monoxide detectors to include the devices “propensity to record false alarms”); see also Intec Controls, Carbon Monoxide Detectors Certified to ANSI/UL 2017 & 2075, PR.COM, July 10, 2010, available at http://www.pr.com/press-release/247664 (on file with the McGeorge Law Review) (describing the stringent ANSI/UL standards for carbon monoxide detectors and stating that an approved detector was “the new standard for CO detection products in the commercial market,” and stating that approved devices “have undergone
B. Concerns with Chapter 19

By creating a new building standard by statute, Chapter 19 circumvents the standard agency process for adopting new building standards.\textsuperscript{51} The standard agency process has several benefits, including input from the public and information from experts in the field.\textsuperscript{52}

While carbon monoxide detectors may help save lives, they can only warn of dangers that are already present, and their technology remains imperfect.\textsuperscript{53} A carbon monoxide detector is not a replacement for caution and good appliance maintenance, and Chapter 19 may cause owners to become overly-confident about their protection against carbon monoxide poisoning.\textsuperscript{54}

Also, because there are no building standards detailing how many detectors a building requires or where the detectors should be located, Chapter 19 relies on the manufacturer’s instructions to provide owners with this information.\textsuperscript{55} These instructions could be biased and may lead owners to purchase more devices than necessary, or cause inconsistent obligations for owners and landlords.\textsuperscript{56} A more direct way to remove inconsistencies would be to require installation according to building standards regulations, which have since been adopted to require carbon monoxide detectors in all new buildings.\textsuperscript{57}

However, parties opposing the bill were at least successful in having it amended to require the State Fire Marshall to review the manufacturers’ instructions and ensure they are consistent with building regulations.\textsuperscript{58}

\begin{footnote}
51. See ASSEMBLY COMMITTEE ON HOUSING AND COMMUNITY DEVELOPMENT, COMMITTEE ANALYSIS OF SB 183, at 8 (June 15, 2010) (quoting the governor as vetoing a similar bill because “[p]lacing building standards in statute rather than regulation circumvents the existing state regulatory adoption process and excludes the input of safety and construction experts”).

52. ASSEMBLY COMMITTEE ON HOUSING AND COMMUNITY DEVELOPMENT, COMMITTEE ANALYSIS OF SB 183, at 8 (June 15, 2010)

53. See INTERNATIONAL CODE COUNCIL, supra note 40, at 1 (stating that carbon monoxide detectors perform poorly).

54. See id. at 2 (quoting the EPA stating that carbon monoxide detectors are no substitute for good appliance maintenance).

55. See CAL. HEALTH & SAFETY CODE § 17926(b) (enacted by Chapter 19) (requiring owners install carbon monoxide detectors in compliance with manufacturer’s instructions OR building standards).

56. See id. (requiring owners install carbon monoxide detectors with their own funds).

57. See ASSEMBLY COMMITTEE ON JUDICIARY, COMMITTEE ANALYSIS OF SB 183, at 4 (June 29, 2010). “Because the California Building Standards Commission has already approved regulations that will require carbon monoxide detectors in all new construction, this bill would only apply to existing structures.” Id. Matching the statutory standard to the regulatory standard would ensure that buildings standards are uniform for both existing and new buildings. Id.

58. See CAL. HEALTH & SAFETY CODE § 13263(a)(1) (enacted by Chapter 19) (requiring the State Fire Marshall to review instructions as well as devices).
\end{footnote}
V. CONCLUSION

Chapter 19’s carbon monoxide detector certification process will likely ensure the quality of carbon monoxide detectors in California is adequate to protect citizens and avoid technological problems.\(^59\) Chapter 19 requires carbon monoxide detectors through a statutory mandate, rather than through the Building Standards Code, which makes Chapter 19 applicable only to existing buildings.\(^60\) Although this circumvents some benefits of the regulatory process, it will likely lead to owners quickly installing detectors in more homes.\(^61\)

Chapter 19’s main purpose is to save Californians from carbon monoxide poisoning.\(^62\) Although carbon monoxide detectors are imperfect,\(^63\) Chapter 19 provides a necessary step to prevent future accidents from occurring.\(^64\)

\(^{59}\) See Intec Controls, supra note 50 (stating that achieving certification requires high quality detectors which “have undergone performance tests including physical endurances, cross sensitivity to other gases, validation for accuracy, provision of interference-free signals, and other stress assessments in extreme lab environments”).

\(^{60}\) See CAL. HEALTH & SAFETY CODE § 18909(a) (stating that building standards apply only to new construction, repairs, alterations, etc.).

\(^{61}\) See ASSEMBLY COMMITTEE ON HOUSING AND COMMUNITY DEVELOPMENT, COMMITTEE ANALYSIS OF SB 183, at 8 (June 15, 2010) (quoting the Governor’s concerns about circumventing the regulatory process).

\(^{62}\) See CAL. HEALTH & SAFETY CODE § 13260 (enacted by Chapter 19) (naming the chapter the Carbon Monoxide Poisoning Prevention Act, indicating the purpose of the act).

\(^{63}\) INTERNATIONAL CODE COUNCIL, supra note 40.

\(^{64}\) See McGreevy, supra note 49 (stating Chapter 19 will prevent senseless deaths); CAL. HEALTH & SAFETY CODE § 13260(e) (enacted by Chapter 19) (stating the legislative finding that equipping every home with a carbon monoxide detector would cut accident related costs by 93 percent).
Giving Life: Increasing Organ Donation and Creating an Altruistic Organ Donation Registry

Rebekah Morrissey

Code Sections Affected

Health & Safety Code §§ 7152, 7152.1, 7152.2 (new); Vehicle Code § 12811 (amended).

SB 1395 (Alquist); 2010 STAT. Ch. 217

I. INTRODUCTION

On June 9, 2008, at Apple’s Worldwide Developers Conference, Steve Jobs, co-founder and CEO of Apple, took the stage to unveil the newest version of the iPhone. However, the majority of the media coverage did not focus on the iPhone’s new features; rather, it focused on Jobs’ gaunt appearance. In 2008 and 2009, Jobs cancelled several public appearances, which caused the press to speculate about his health. In truth, Jobs’ liver was failing and he needed a transplant. In 2009, 3,400 Californians waited for liver transplants, “671 got one[,] 400 died,” and the rest continued to wait. Fortunately for Jobs, he had the resources and knowledge to secure a liver from a donor in Tennessee. He found his donor liver through a process called “multiple listing,” which involves traveling the country, receiving evaluations, and gaining a place on the organ donor list at multiple hospitals. However, the majority of people waiting for organs cannot afford multiple listings, even though this increases the chances of finding a viable tissue match. “Insurance companies only cover one listing” due to the expense of testing at multiple hospitals.

After his transplant, Jobs got involved in raising awareness about organ donation in order to convince more people to become organ donors. At a dinner


4. Id.

5. Id.

6. See id. (noting that many wealthy Americans, like Jobs, attempt to get on various donor lists throughout the United States).

7. Id.

8. Id.

9. Id. (“[G]etting listed is very expensive.”).

10. See id. (“And so, in a departure from a largely apolitical career, Steve decided to do something about it.”).
in December of 2009, Jobs spoke to Maria Shriver, wife of Governor Schwarzenegger, about increasing the number of donors in California.\footnote{Id.} She in turn spoke to the Governor.\footnote{Id.} Believing this idea had merit, the Governor contacted State Senator Alquist “a long time advocate for organ donation.”\footnote{Id.} After sitting on Senator Alquist’s desk for several years, Alquist introduced SB 1395, “[a]ll thanks to Steve Jobs—and his now-departed liver.”\footnote{Id.}

II. LEGAL BACKGROUND

Existing law prohibits the sale or purchase of organs for transplant.\footnote{CAL. HEALTH & SAFETY CODE § 7150.75 (West Supp. 2010).} Any person who needs an organ transplant must receive the organ as a gift, and the hospital can only charge a reasonable fee for the organ’s procurement and transplantation.\footnote{See id. (“A person [or hospital] may only charge a reasonable amount for the removal, processing, preservation, quality control, storage, transportation, implantation, or disposal of a part.”).} Californians may donate at death or during their lifetime.\footnote{Id. § 7150.20.} To donate at death, a donor must do one of the following: indicate a wish to donate on his or her driver’s license and register with a donor database; directly register as a donor with a donor database; specify a wish to donate in a will; or have an authorized agent give consent at the donor’s death.\footnote{Id. § 7150.20(a)(4).} To donate during their lifetime, donors must sign a donor card or other record indicating a wish to donate, and “at least two adults [must witness the signature], at least one of whom is a disinterested witness.”\footnote{Id. § 7150.9.}

Federally-approved Organ Procurement Organizations (OPOs) maintain California’s organ donation registry.\footnote{SENATE FLOOR, COMMITTEE ANALYSIS OF SB 1395, at 4 (May 12, 2010).} The OPOs established a non-profit organization called Donate Life California, whose primary function is the maintenance of the California Organ and Tissue Donation Registry, which compiles the names of people willing to donate organs upon their death.\footnote{Press Release, Office of the Governor of the State of California, Gov. Schwarzenegger Announces Legislation to Increase Organ Donation Opportunities (Mar. 19, 2010) [hereinafter Governor’s Press Release] (on file with the McGeorge Law Review) (noting that SB 1395 would create the “nation’s first living donor registry”).} Under existing law, there is no registry that maintains a list of donors willing to donate during their lifetime.\footnote{Id. § 7150.75 (West Supp. 2010).}

Prior to 2005, the Department of Motor Vehicles (DMV) asked applicants if they wished to join the registry and provided forms for applicants to mail directly
to Donate Life California in order to enroll. A pink “donor” sticker attached to the front of a driver’s license signaled an intention to donate. The donor registry added the applicant to the registry only when Donate Life California received the mailed form. In 2005, the DMV began electronically submitting the names of those who elected to become organ donors directly to Donate Life California.

The existing application for a driver’s license provides a space where the applicant may consent to become an organ donor. If the applicant indicates a wish to donate, the DMV will print “DONOR” in a pink dot on the front of the license. An employee of the DMV will direct the applicant to the back of the application, which contains information on how the program works and how to cancel enrollment. Drivers under the age of eighteen may become donors, but the final decision regarding donation belongs to a parent or legal guardian.

III. CHAPTER 217

Chapter 217 creates a non-profit organization called the Altruistic Living Donor Registrar (ALDR). The ALDR will compile and maintain a list of people in California willing to donate kidneys during their lifetime. The registry will share the information of willing donors with “federally designated organ procurement organizations[] and transplant centers in California.” The ALDR may receive donations from private sources and will make information available to the public regarding the “number of donors on the registry,” “changes in the number of donors on the registry,” and “general characteristics of donors.”

Chapter 217 also provides that after July 1, 2011, any application or renewal of a driver’s license in California will include a yes or no check box asking applicants if they wish their organs to be donated when they die. An employee
of the DMV must verbally ask the applicant if he or she would like to register, and provide information about the program and how to cancel enrollment.³⁶

IV. ANALYSIS

The ADLR allows live donors to join the registry and avoid questioning of their motives because the fear of selling organs for profit.³⁷ The small changes to driver’s license forms aim to encourage more people to donate their organs.³⁶

A. The Need for an Altruistic Donor Registry

Chapter 217 creates the first state registry of kidney donors willing to give an organ to a stranger during their lifetime.³⁹ With more than 100,000 people in the United States today on an organ transplant list, and approximately 21,000 of them Californians, proponents of the ALDR argue that creating this registry will allow doctors to match willing donors with those in need of transplants.⁴⁰ The current system of registration for donation necessitates the ALDR.⁴¹ The number of patients needing kidneys is around 16,000 and counting, and the current system cannot provide enough kidneys for those in need of transplants.⁴² President of Donate Life, Bryan Stewart, highlighted the inadequacy of the current registry to address donation needs in a speech announcing this bill.⁴³ Mr. Stewart noted that “even if every actual deceased organ donation opportunity was authorized by a registered donor or the donor’s family, we could not keep up with the growing need.”⁴⁴ Altruistic donation, facilitated by the creation of the ALDR, helps to bridge the gap between deceased donors and the growing number of people needing kidney transplants.⁴⁵

With such a pressing demand for organs, it would likely surprise many Californians to realize that donating a kidney to a stranger is often a long and difficult process.⁴⁶ The process of organ donation itself provides another reason the ALDR is needed: altruistic donors who elect to donate to a complete stranger

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³⁶. Id. § 12811(b)(2)-(3) (amended by Chapter 217).
³⁷. See Erin Allday, Living Donor Registry Would Be 1st in Nation, S.F. CHRON., Apr. 19, 2010, at A1 (“It’s not easy for Good Samaritan organ donors to give up a kidney or other tissues they don’t necessarily need, despite the fact there are tens of thousands of people waiting for transplants.”).
³⁹. Governor’s Press Release, supra note 22.
⁴⁰. Id.
⁴¹. Id.
⁴². See Governor’s Remarks, supra note 38 (quoting Bryan Stewart).
⁴³. Id.
⁴⁴. Id.
⁴⁵. Id.
⁴⁶. Allday, supra note 37.
are often met with skepticism by medical professionals who fear that the donors may have been coerced or paid for their organs.\textsuperscript{47} Questioning the motives of donors attempting to engage in a selfless and generous act allows the fear of selling organs, an illegal act in the United States, to slow down the transplant process.\textsuperscript{48}

Doctors and medical ethicists often struggle to determine why an otherwise healthy individual would undergo the risks of surgery to donate a kidney to a complete stranger.\textsuperscript{49} The skepticism of physicians is due largely to the rareness of altruistic donation, which accounts for less than one percent of live donations in the United States.\textsuperscript{50} For example, a physician in Boston began researching the motivations behind organ donation from strangers after encountering a patient who asked if he could go out and find his own kidney donor.\textsuperscript{51} The physician met with a transplant board to determine whether it would even be “morally appropriate” to approve such a transplant.\textsuperscript{52} Under the ALDR, healthy people wishing to donate kidneys will not meet the skepticism and questioning common under existing law, and those who need transplants will receive them more quickly.\textsuperscript{53}

B. Increasing Donor Registration

The other component of Chapter 217 makes a relatively small change to the DMV protocol for registering donors who wish to donate organs upon death.\textsuperscript{54} Instead of allowing drivers to opt-in to the donor registry, Chapter 217 mandates a yes-or-no answer to the question of organ donation.\textsuperscript{55} Although the DMV cannot deny a driver’s license to anyone who does not answer the question, it is likely that the number of organ donors will increase given that “only about half of people who would donate actually bother to sign up.”\textsuperscript{56} By making the choice

\textsuperscript{47} Id.
\textsuperscript{48} See id. (citing the case of a kidney transplant recipient whose doctors suspected coercion or payment because the donation was to a friend’s nanny).
\textsuperscript{49} David Steinberg, Kidneys and the Kindness of Strangers, 22 HEALTH AFFAIRS 184, 184-87 (2003), available at http://content.healthaffairs.org/content/22/4/184.short (on file with the McGeorge Law Review); Allday, supra note 37.
\textsuperscript{50} Steinberg, supra note 49. While donation of a kidney to a stranger is very rare in the United States, it is actually illegal in other countries. Id. The United Kingdom, Germany, and India all prohibit kidney donation to a stranger. Id. The United Kingdom requires living donors to provide proof of a relationship to the donee, such as a marriage certificate or photos documenting a blood relationship or close friendship. Id.
\textsuperscript{51} Id.
\textsuperscript{52} Id.
\textsuperscript{53} See id. (examining the problems faced by altruistic donors).
\textsuperscript{55} Id.
\textsuperscript{56} Id.
to join the registry more explicit, supporters hope more people who are willing to donate organs will finally take the step to join the registry.57 A North Carolina study found that nearly twenty percent of families ignored the wishes of the deceased when it came to organ donation, and only thirty-seven percent of families agreed to donate when DMV records did not indicate consent.58 However, in North Carolina, the DMV cannot automatically enroll those who list a preference to be an organ donor on their DMV application.59

While North Carolina’s system differs from California’s, the basic principle translates: without enrollment, many people willing to donate will not have their wishes carried out.60 Supporters of Chapter 217 contend that simply asking one additional question of applicants—“Do you want to be an organ donor?”—may double the number of donors on the registry.61

V. CONCLUSION

Chapter 217 aims to increase the number of registered organ donors in California and help save the lives of the thousands of Californians waiting for organs.62 By creating the ALDR, Chapter 217 hopes to fill the void between the growing need for organs and the current donor shortfall.63 Shepherded into existence by Steve Jobs, one of the wealthiest Americans, Chapter 217 helps to ensure that money is no longer as important a factor in determining who will receive a kidney transplant.64 As the need for organs grows, the small change to the driver’s license application ensures that Californians willing to donate can do so.65 “Organ donation is one of the kindest and the simplest and the most generous and the most powerful actions that each and every one of us can take.”66 What started as a simple idea, became a powerful piece of legislation, and will hopefully lead to many kind and generous acts that give the gift of life to many Californians.67

57. Id.
59. Id. (noting that DMV designations are not “legally binding”).
60. REAL NUMERACY, supra note 54.
61. Governor’s Remarks, supra note 38 (quoting Steve Jobs).
62. Id. (citing Governor Schwarzenegger)
63. Id.
64. Carlson, supra note 1.
65. REAL NUMERACY, supra note 54.
66. Governor’s Remarks, supra note 38.
67. Id.