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Code Sections Affected

Business and Professions Code § 4076 (amended).
SB 292 (Speier); 2003 STAT. Ch. 544.

"As pharmacists, it is difficult for us to believe that we, or a technician, could receive a prescription on one drug, prepare the prescription label correctly, perform a drug review and counsel the patient, and yet have counted and poured the wrong drug into the prescription bottle. Yet, each of us knows this can occur."[1]

I. INTRODUCTION

On March 13, 2003, a power outage that interrupted the Kaiser Permanente Northern California pharmacy computer system prompted that organization to contact 4,700 patients who may have received prescription drugs with labeling errors.[2] According to Kaiser Permanente, the errors potentially ranged from including wrong prescription numbers, providing incorrect instructions, or even dispensing the wrong drug.[3]

In a regularly updated study of claims against pharmacists, Pharmacists Mutual Insurance Company reports that over half of all claims logged are for pharmacists dispensing the "wrong drug."[4] Furthermore, in an analysis of claims reported to the California Board of Pharmacy between June 1997 and March 2000, the Campaign for Patient Safety reports that having either the wrong drug in the right bottle or the right drug in the wrong bottle is the most common result of dispensing error.[5] In addition to indicating that patients are at risk of taking the wrong medication even after consulting with their pharmacist, the analysis notes

1. Pharmacists Mutual Insurance Company, *Pharmacists Mutual Claims Study–2000*, The Mechanical Errors, *at* http://qcletter.pmcqc.com/study_pg_3.html (last visited Feb. 27, 2004) [hereinafter *Claims Study*] (copy on file with the *McGeorge Law Review*).

2. Press Release, Kaiser Permanente California News Bureau, Statement from Kaiser Permanente Northern California Regarding Pharmacy Computer Problem, (Mar. 17, 2003), *at* http://www.kaiserpermanente.org/locations/california/newsroom/releases/ca031703.html (copy on file with the *McGeorge Law Review*).

3. *Id.*

4. *Claims Study*, *supra* note 1.

5. *See* Soren Tjernell, SB 292 (Speier) Background, at 2 (2003) (copy on file with the *McGeorge Law Review*) (describing the Campaign for Patient Safety's study as part of a background for the impetus of SB 292).

that most pharmacy errors are never reported or scrutinized.[6]

Reports such as these have prompted concern for patient safety.[7] Between 1983 and 1993, the number of outpatient medical visits in the United States increased by 75%, while inpatient hospital days decreased by 21%.[8] This suggests that more and more, patients are taking medications without the supervision of medical personnel, relying instead on instructions given by doctors and pharmacists.[9] Seniors, in particular, are at greater risk of medication error, as they have more prescriptions filled, on average, than younger groups.[10]

The more medications a patient takes, the higher the chance of disassociating pills from their containers by either spilling the medication or mixing it with others in daily dispensers, creating a dangerous situation if the patient loses track of which pill matches which prescription.[11]

Chapter 544 recognizes the problem created by labeling errors and the potential for accidental mix-ups for patients with multiple prescriptions.[12] The new law attempts to safeguard patients by requiring drug labels on outpatient prescription containers to contain a physical description of the drug itself, including color, shape and identifying codes.[13] By giving guidance on the label, the law seeks to provide a safeguard reference to both pharmacists preparing prescriptions and patients consuming them.[14]

II. LEGAL BACKGROUND

A. *Existing California Law*

1. Business and Professions Code Section 4076

Pharmacists must properly label every prescription drug container dispensed.[15] Section 4076(a) of the Business and Professions Code provides the requirements for prescription drug container labels in California.[16] Prior to the

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6. *Id.*

7. *Id.* at 1-2.

8. David P. Phillips, et al., *Increase in US Medication-Error Deaths Between 1983 and 1993*, 351 THE LANCET 643 (1998).

9. *Id.*

10. *See* Tjernell, *supra* note 5, at 3 (describing prescription label safety concerns regarding senior citizens).

11. *Id.*

12. *See generally* SENATE RULES COMMITTEE, COMMITTEE ANALYSIS OF SB 292, at 2 (May 27, 2003) (listing the changes to the law made by Chapter 544).

13. *Id.*

14. *See id.* at 3 (stating the author's goal of SB 292: "to reduce the number of errors made in the administration and consumption of prescription medication").

15. *See* CAL. BUS. & PROF. CODE § 4076(a) (West 2003) (listing the information that must be included on every prescription drug label).

16. *Id.* § 4076(a)(1)-(10).

passage of Chapter 544, the law required the following ten essential items to be provided on prescription labels: (1) name or generic name of the drug along with the manufacturer, (2) directions for use, (3) name of the patient or patients, (4) name of the prescriber, (5) date of issue, (6) name and address of the pharmacy and prescription number, (7) strength of the drug, (8) quantity of the drug, (9) expiration date of effectiveness of the drug, and (10) if requested by the patient, the condition for which the drug was prescribed if the condition appears on the prescription.[17] In addition to these label requirements, the California Code of Regulations requires pharmacists in outpatient settings to consult with patients who are receiving any type of medication for the first time.[18]

2. Business and Professions Code Section 4125

As of January 1, 2002, the law requires pharmacies to establish quality assurance programs that document medication errors which can be attributed to the pharmacy or its personnel.[19] This section was enacted in 2000 as a way of requiring pharmacies to assess errors and take appropriate action to prevent recurrences.[20]

3. Health and Safety Code Section 1339.63

This section, also enacted in 2000, focuses on hospitals and clinics and requires them to complete a plan to eliminate or substantially reduce medication errors as a qualification for licensure.[21] These plans are subject to review by the State Department of Health Services and must be implemented by January 1, 2005.[22]

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17. *See* SENATE RULES COMMITTEE, COMMITTEE ANALYSIS OF SB 292, at 1-2 (May 27, 2003) (summarizing the information required by law to appear on prescription labels).

18. *See* CAL. CODE REGS. tit. 16, § 1707.2 (2003) (describing the circumstances under which pharmacists are under a duty to consult with a patient, and the minimum criteria for information the pharmacist is to impart to that patient).

19. CAL. BUS. & PROF. CODE § 4125 (West 2003).

20. *Id.*

21. CAL. HEALTH & SAFETY CODE § 1339.63(a)(1) (West Supp. 2004) (specifying which types of medical facilities are required to complete a medication error reduction plan as a qualification for licensure).

22. *See id.* § 1339.63(a)(2) (describing the State Department of Health Services' approval requirement and specifying the deadline for compliance).

B. Other States

Two other states have implemented similar requirements as those enacted by Chapter 544.[23] In Oregon, the Board of Pharmacy, which promulgates rules for labeling prescription drugs, requires, as of July 1, 2000, that drug labels include a physical description of the drug, including any identifying codes appearing on the tablets or capsules.[24] The Oregon rule exempts those drugs in unit dose or unit of use packaging, and provided a two-year delay in enforcement, which began on July 1, 2002.[25] Also, beginning January 1, 2004, the Wyoming State Board of Pharmacy requires prescription labels in that state to contain a physical description of the drug along with identification codes.[26] The Wyoming rule gives a waiver to "new drugs for the first 120 days on the market and 90 days on drugs for which the national reference file has no description on file."[27]

C. Federal Regulation

At the federal level, the Food and Drug Administration (FDA) is focusing on medication errors occurring in hospitals,[28] which cause more than 7,000 deaths a year.[29] The FDA's plan is to require all admitted hospital patients to wear a bar-coded bracelet that is linked to another barcode on the patient's medical records.[30] All hospital medications will also be bar-coded and, thus, a quick scan of the patient's bracelet, chart, and pills provide a simple check intended to ensure the prescribed medication is received by the right patient.[31]

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23. *See* SENATE COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 292, at 4 (Apr. 28, 2003) (describing laws similar to Chapter 544 enacted in Oregon and Wyoming).

24. *Id.*; OR. ADMIN. R. 855-041-0065(6) (2003), *at* http://arcweb.sos.state.or.us/rules/OARS_800/OAR_855/855_041.html (last visited Feb. 27, 2004) (copy on file with the *McGeorge Law Review*).

25. OR. ADMIN. R. 855-041-0065(6)(k), *at* http://arcweb.sos.state.or.us/rules/OARS_800/OAR_855/855_041.html (last visited Feb. 27, 2004) (copy on file with the *McGeorge Law Review*).

26. *See* SENATE COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 292, at 4 (Apr. 28, 2003) (describing laws similar to Chapter 544 enacted in Oregon and Wyoming).

27. Rules of Practice and Procedure of the Wyoming State Board of Pharmacy, ch. 2, § 11(b), *at* http://soswy.state.wy.us/rules/5055.pdf (last visited Sept. 28, 2003) (copy on file with the *McGeorge Law Review*).

28. Interview with Soren Tjernell, Senate Fellow, Office of Senator Jackie Speier (June 26, 2003) [hereinafter Tjernell Interview] (notes on file with the *McGeorge Law Review*).

29. *See* Vicki Kemper, *FDA Proposes Bar Coding for Hospital Medications*, L.A. TIMES, Mar. 14, 2003, at 15 (stating that the improper administration of medications in hospital has killed more than 70,000 patients in the last decade).

30. *Id.*

31. *Id.*

III. CHAPTER 544

Chapter 544 makes an important addition to the list of criteria required on prescription labels.[32] The new law adds an eleventh requirement to the list of essential items enumerated by section 4076 of the Business and Professions Code.[33] This new provision states, "Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules."[34] This additional information can be printed on an auxiliary label affixed to the container.[35] However, drugs that are within their first 120 days on the market and are within the 90 days during which the national reference file has no description are exempt from the new requirement.[36] In addition, prescriptions dispensed by veterinarians are exempt,[37] as are, "[d]ispensed medications for which no physical description exists in any commercially available database."[38]

Finally, the new law provides one further important exemption. The physical description requirement applies only to outpatient pharmacies.[39] Thus, hospital pharmacies are not bound,[40] nor are prescriptions administered directly to patients by licensed individuals in licensed facilities.[41]

The new law, however, provides that it will only become operative if the Board of Pharmacy fails to enact regulations "that mandate the same labeling requirements" as Chapter 544 requires before January 1, 2006.[42]

IV. ANALYSIS OF THE NEW LAW

As compared to the bill originally introduced, Chapter 544 effects a far less drastic change on current drug labeling requirements than initially intended.[43] The first version of the bill required that, in addition to previously required items on

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32. *See* Cal. BUS. & PROF. CODE § 4076(a)(ii) (amended by Chapter 544) (requiring a physical description of the drug on prescription labels).

33. *See* SENATE RULES COMMITTEE, COMMITTEE ANALYSIS OF SB 292, at 2 (May 27, 2003) (summarizing existing law and additions made by SB 292).

34. CAL. BUS. & PROF. CODE § 4076(a)(11)(A) (amended by Chapter 544).

35. *Id.* § 4076(a)(11)(C).

36. *Id.* § 4076(a)(11)(A)(ii).

37. *Id.* § 4076(a)(11)(A)(i).

38. *Id.* § 4076(a)(11)(A)(iii).

39. *Id.* § 4076(a)(11)(B).

40. *See* Tjernell, *supra* note 5, at 3 (comparing SB 292 to similar laws in Oregon and Wyoming and explaining exemptions in SB 292).

41. CAL. BUS. & PROF. CODE § 4076(d) (amended by Chapter 544) (specifying licensed individuals pursuant to the Medical Practice Act, Nursing Practice Act or Vocational Nursing Practice Act and licensed facilities pursuant to section 1250 of the Health and Safety Code).

42. *Id.* § 4076(a)(11)(D).

43. *See* Tjernell Interview, *supra* note 28 (admitting that the law as modified by the amendments is much more easily adaptable to current drug labeling systems than was the original version of the law).

drug labels, a color image of the pill or capsule must appear.[44] This proposed requirement gained very strong support among senior citizen and patient-safety advocates.[45] The author of the legislation stated that an image of the medication on drug labels seemed like an intuitive step regarding drug label safety.[46] Supporters also noted that an image would be especially helpful for those with vision problems who could compare colors on pills to label images, as well as for non-English speaking patients.[47]

The mandate of having to print a color image on every label, however, drew strong opposition from the California Pharmacists Association, Rite Aid, and Kaiser Permanente.[48] In addition to the logistical problems and high costs associated with color printing on small labels, the opponents envisioned scenarios of images which inadvertently looked very different from the pills contained in the bottles, causing confusion among patients.[49]

In response to this opposition, amendments to the new law changed the image requirement to a physical description, and added exemptions.[50] Additionally, a two-year window of non-enforcement was added which, together with the exceptions, satisfied most of the opponents.[51] Borrowing language from the Wyoming regulation, an exemption was added for drugs that are new to the market.[52] Also, following Oregon's lead, the law postpones enforcement for two years, providing ample time for labeling software and pharmacies to adapt to the new requirement.[53] Acknowledging that the purpose of the law is not to force pharmacists to have to reprogram their labeling software with descriptions of

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44. SENATE COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 292, at 5 (Apr. 28, 2003).

45. *See id.* at 6 (listing supporters of the proposed law, including, e.g., the Campaign for Patient Safety and the Congress of California Seniors).

46. Tjernell Interview, *supra* note 28.

47. Letter from Frederick S. Mayer, R.Ph., M.P.H., President, Pharmacists Planning Service, Inc., to Senator Jackie Speier, Cal. State Senate (Mar. 12, 2003) [hereinafter Mayer Letter] (on file with the *McGeorge Law Review*); Campaign for Patient Safety, Support for SB 292 (Speier) (copy on file with the *McGeorge Law Review*).

48. *See* SENATE COMMITTEE ON BUSINESS AND PROFESSIONS, COMMITTEE ANALYSIS OF SB 292, at 6 (Apr. 28, 2003) (listing California Pharmacists Association, Rite Aid, and Kaiser Permanente as opponents of the proposed law in an early Committee Analysis).

49. *See* Letter from Peter Kellison, Legislative Advocate, The Kellison Company, to Senator Jackie Speier, Cal. State Senate (Apr. 2, 2003) (on file with the *McGeorge Law Review*) (opposing the law on behalf of the California Pharmacists Association and discussing the potential costs associated for pharmacists in purchasing software and color printers); *see also* Letter from Alan Edelstein, Donald Gilbert, Michael Robson, and Trent Smith, Edelstein and Gilbert, to Members of the Senate Business and Professions Committee (Apr. 4, 2003) (on file with the *McGeorge Law Review*) (opposing the law on behalf of Rite Aid, and discussing an example of a situation where the color on a printed label may look different than the actual pill, causing confusion for the patient).

50. *See* Tjernell Interview, *supra* note 28 (stating that Rite Aid and Kaiser Permanente ceased opposition once amendments and exemptions were added to the law).

51. *Id.*

52. *See id.* (stating that the new drug provision was essentially borrowed straight from the language of the Wyoming law).

53. *See id.* (stating that the purpose of providing the two-year window was to give a fair amount of time to those who need to comply, as Oregon had done in implementing its law).

pills, the bill was amended to state that only pill descriptions available on commercial drug databases are covered by the new requirement.[54] Thus, pharmacists and their software providers should have little trouble adapting labeling systems, especially considering the two-year period which they have to complete the modifications.[55] Indeed, two major pharmacy chains in California, Longs Drugstores and Walgreens, already use some type of drug identification on labels.[56] Additionally, both Rite Aid and Kaiser Permanente ceased opposition to the new law once amendments were made.[57]

In response to pressure from the California Veterinary Medical Association (CVMA), the law was amended to exempt prescriptions filled by veterinarians.[58] The CVMA felt that the veterinarians, who dispense pills for animals themselves as well as prescribe large quantities of drugs used in food-producing animals, would be affected by the law.[59] CVMA claimed that veterinarians are less equipped with software or resources than doctors and pharmacists in the human medical field.[60] Because the concern by the author was for human patient safety, the exemption was added and opposition from the CVMA ceased.[61]

Chapter 544 admittedly focuses on safety in the outpatient setting.[62] The law only applies to outpatient pharmacies, thus leaving in-hospital medication labels unaffected.[63] The limitation to prescriptions taken without medical supervision is justified by the proponents of the new law by noting recent efforts by the FDA focusing on tighter control of medication-error in hospitals,[64] and the fact that many hospitals are already using much more sophisticated error-control techniques than outpatient pharmacies.[65]

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54. *See id.* (describing two main commercial databases that exist which pharmacists use to obtain information about drugs and stating that there was no intent to force pharmacists to program databases in the law).

55. *Id.*

56. Mayer Letter, *supra* note 47.

57. *See* Letter from Alan Edelstein, Donald Gilbert, Michael Robson, and Trent Smith, Edelstein and Gilbert, to Senator Jackie Speier, Cal. State Senate (May 22, 2003) (on file with the *McGeorge Law Review*) (removing Rite Aid's opposition after the color image requirement was amended to require that only a physical description appear on the label); *see also* Letter from J. Michael Hawkins, Legislative Representative and Senior Counsel, Kaiser Permanente, to Senator Jackie Speier, Cal. State Senator (May 21, 2003) (on file with the *McGeorge Law Review*) (adopting a "neutral" position on the law on behalf of Kaiser Permanente after the first amendment was made).

58. Tjernell interview, *supra* note 28.

59. *See* Letter from Michael F. Dillon, Michael F. Dillon & Associates Inc., to Senator Jackie Speier, Cal. State Senator (Apr. 23, 2003) (on file with the *McGeorge Law Review*) (stating the position of "oppose unless amended" on behalf of the CVMA, discussing the concerns of the veterinary community and requesting the law be restricted to human medications only).

60. *Id.*

61. Tjernell interview, *supra* note 28.

62. *Id.*

63. *See* Tjernell, *supra* note 5, at 3 (comparing SB 292 to similar laws in Oregon and Wyoming and explaining exemptions in SB 292, stating that it exempts hospital pharmacies).

64. Tjernell interview, *supra* note 28; *see also* Kemper, *supra* note 29 (describing the FDA's new proposals regarding medication error monitoring in hospitals).

65. *See* Tjernell interview, *supra* note 28 (describing a method used at Kaiser Permanente hospitals,

By limiting the description requirements to outpatient prescriptions, Chapter 544's effectiveness is unclear. Oregon is the only other state that has a similar law already in place and its effectiveness is inconclusive.[66] Adverse drug reactions caused by medication error occurring outside of controlled medical facilities are more difficult to study, and as a result, it is difficult to say with certainty whether the additional labeling requirements will help consumers.[67] The California Pharmacists Association, the only major opponent to the law, insists that improved enforcement of existing consultation requirements for pharmacists would better increase consumer awareness and safety without an undue burden upon an already expensive pharmaceutical industry.[68] The numerous patient-advocate groups that support the law, however, coupled with the minimal resistance from drug companies and pharmacy chains, suggest that the potential safety improvement outweighs any burden that will be felt by those conforming to the new labeling requirement.[69]

V. CONCLUSION

Drug labeling errors and prescription pill mix-ups are a common danger to patients.[70] Chapter 544 takes a modest, but important step toward safeguarding patients against these potentially deadly situations.[71] By adding the requirement of a physical description of the medication to outpatient prescription drug labels, patients and pharmacists have a further check to make sure the pill in the bottle is the correct one.[72] Although the law was first introduced as an attempt to put a color image of pills on bottles, the physical description requirement and its exceptions serve as an effective compromise between pursuing the goal of patient safety and integrating current pharmacy practices and capabilities.

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whereby a picture of a pill is displayed to a pharmacist filling a bottle next to a live camera image of the pill that is actually going into the bottle for comparison).

66. *See id.* (stating that there are no concrete studies available for which to track effectiveness of similar law in Oregon).

67. *See* ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 292, at 2 (July 8, 2003) (stating that estimates of the number of medication errors and adverse drug events occurring in outpatient settings are harder to determine than those occurring in hospital settings).

68. Letter from Peter Kellison, Legislative Advocate, The Kellison Company, to Senator Jackie Speier, Cal. State Senator (May 20, 2003) (on file with the *McGeorge Law Review*).

69. *See* ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 292, at 4 (July 8, 2003) (listing eight organizations supporting the law, and only one opposed).

70. *See id.* at 2-3 (describing several studies showing the prevalence of medication error).

71. *See* Letter from William Powers, Legislative Director, Congress of California Seniors, to Senator Jackie Speier, Cal. State Senator (May 20, 2003) (on file with the *McGeorge Law Review*) (describing the law as "a modest step to deal with a very serious problem").

72. *See* ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 292, at 2 (July 8, 2003) (stating that the purpose of the bill is to "reduce the number of mistakes made in the administration and consumption of prescription medications . . .").