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McGeorge Law Review

Volume 44 | Issue 3 Article 21

1-1-2013

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Recommended Citation

Amanda Iler, *Chapter 709: Expanding Access to Prescription Medication for Indigent Patients*, 44 McGeorge L. Rev. 712 (2013).
Available at: https://scholarlycommons.pacific.edu/mlr/vol44/iss3/21

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Chapter 709: Expanding Access to Prescription Medication for Indigent Patients

Amanda Iler

Code Sections Affected

Health and Safety Code § 150202.5 (new), §§ 150200, 150201, 150202, 150204, 150205 (amended).
SB 1329 (Simitian); 2012 STAT. Ch. 709.

I. INTRODUCTION

In 2005, a Stanford medical student entered a contest, sponsored by Palo Alto Senator Joe Simitian, called "There Oughta Be a Law."[1] The student's idea was simple: to give counties the ability to redistribute unused medication to indigent patients.[2] In California, healthcare facilities dispose of millions of dollars' worth of unused, unexpired medication each year,[3] while patients without access to necessary medications number in the millions.[4] The student's idea not only won the contest, it became law in 2005.[5]

Since then, the counties of Santa Clara and San Mateo have successfully implemented drug redistribution programs.[6] But a nonprofit organization called Supporting Initiatives to Redistribute Unused Medicine (SIRUM)[7] contemplated that the donation process and redistribution process could be easier for other healthcare facilities.[8] The organization approached Senator Simitian "about improving the 2005 legislation."[9] Senator Simitian subsequently introduced

1. Judith Pelpola, *State Senator Unveils Bill at Haas Center*, STANFORD DAILY (Feb. 27, 2012), http://www.stanforddaily.com/2012/02/27/state-senator-unveils-bill-at-haas-center-2/ (on file with the *McGeorge Law Review*).

2. *Id.*

3. *Id.*

4. *See* SENATE COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 1329, at 3 (Apr. 11, 2012) (describing how a 2009 survey found that 2.2 million Californians did not have prescription drug insurance).

5. Pelpola, *supra* note 1.

6. *See* SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT, COMMITTEE ANALYSIS OF SB 1329, at 6 (May 7, 2012) (stating that more than 200,000 pills have been redistributed and $600,000 worth of drugs donated).

7. *See generally* Pelpola, *supra* note 1 ("SIRUM [a Stanford-based organization] runs a website that healthcare facilities with surplus medications can log onto and scan in the medications they have, which the site then allocates to clinics that have requested that type of medication."); Chris Kenrick, *Stanford Team Creates System to Recoup Unused Drugs*, PALO ALTO ONLINE NEWS (Feb. 27, 2012, 9:54 AM PST), http://www.paloaltoonline.com/news/show_story.php?id=24457 (on file with the *McGeorge Law Review*) (reporting that the winner of the "There Oughta Be a Law" contest, Dr. Josemaria Paterno, is now an advisor to SIRUM).

8. Pelpola, *supra* note 1.

9. *Id.*

Chapter 709.[10] Chapter 709 makes it easier for counties to implement drug repository and distribution programs.[11] It also increases the number of facilities that may donate and distribute medication.[12]

II. LEGAL BACKGROUND

Prior to Chapter 709, Section 150204 of the California Health and Safety Code permitted counties to implement drug repository and distribution programs by ordinance only.[13] Existing law details protocol and procedures for establishing a program, including the types of approved medications that pharmacies may distribute and safety standards for the medication.[14] When a county established a program, only "licensed skilled nursing" facilities[15]—including those designated for mental health—and "licensed wholesalers and drug manufacturers" could donate unused medication in accordance with section 150204.[16]

Only county-owned or county-contracted pharmacies dispensed donated medication.[17] Pharmacies handled donated medication in one of three ways only: gave it "to an eligible patient," destroyed it, or returned it "to a reverse distributor."[18] Existing law required each participating county to establish eligibility standards for patients receiving medication under a drug repository and redistribution program[19] and to ensure that the medication is free of charge.[20]

Existing law exempts from civil and criminal liability the aforementioned facilities, as well as pharmacists and healthcare officials who accept and dispense drugs in accordance with program standards.[21] The only exceptions to this are noncompliance with specified standards and procedures, bad faith, and gross negligence.[22]

10. *Id.*

11. *See infra* Part IV.B (explaining how Chapter 709 eases the implementation process for counties).

12. SENATE COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 1329, at 2 (Apr. 11, 2012).

13. CAL. HEALTH & SAFETY CODE § 150204 (West 2012); *see also infra* Part IV.B (detailing why establishing drug repository and redistribution programs by ordinance is difficult).

14. *See* HEALTH & SAFETY § 150204 (stating that donated medication may not be a controlled substance, "adulterated, misbranded, or stored under contrary conditions set by the United States Pharmacopoeia," or have been in the "possession of a patient or any individual member of the public").

15. *See generally id.* § 1250 (West 2008) (defining a skilled nursing facility as "a health facility that provides skilled nursing care and supportive care to patients whose primary need is for availability of skilled nursing care on an extended basis").

16. *Id.* §§ 150202–03 (West 2012).

17. *See id.* § 150204 (providing various protocols and procedures—in addition to those described in the text of this article—that counties must follow in establishing a program, including privacy guidelines, medication criteria, and record specifications).

18. *Id.* § 150204(g)(1)–(3).

19. *Id.* § 150204(b)(1).

20. *Id.* § 150204(b).

21. *Id.* § 150205.

22. *Id.* § 150206.

III. CHAPTER 709

Chapter 709 permits a county board of supervisors or public health officer to establish a drug repository and redistribution program, effectively doing away with the ordinance requirement.[23] It also increases the number of facilities allowed to donate and distribute unused medication.[24] Chapter 709 authorizes two additional types of facilities to dispense medication: licensed pharmacies "owned and operated by a licensed primary care clinic"[25] and primary care clinics "licensed to administer and dispense drugs."[26] Chapter 709 exempts these facilities from liability from injury caused by donation or distribution of medication.[27] Chapter 709 also expands how pharmacies may handle donated medication[28]: transfer it to other participating facilities for distribution to eligible patients, dispense it, destroy it, or return it to a reverse distributor.[29]

IV. ANALYSIS

Chapter 709 primarily expands existing law,[30] with supporters anticipating a measurable, positive effect.[31] They cite three specific areas the new law will impact most dramatically: increasing access to indigent patients' access to medication,[32] county participation,[33] and environmental impact.[34]

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23. *Id.* § 150204(a)(1) (amended by Chapter 709).

24. *Id.* §§ 150201, 150204(a)(2) (amended by Chapter 709); *id.* at § 150202 (amended by Chapter 709) (expanding the list of facilities that may donate to include licensed general acute care hospitals, acute psychiatric hospitals, residential care facilities, correctional treatment centers, intermediate care facilities, and certain types of pharmacies).

25. *Id.* § 150201(a)(2) (amended by Chapter 709).

26. *Id.* § 150201(a)(3) (amended by Chapter 709).

27. *Id.* § 150205 (amended by Chapter 709) (stating that entities who are authorized to donate, accept, and dispense will not be liable for any injuries, as long as they were in compliance with the guidelines enumerated in the Health and Safety Code; this is the same immunity afforded under the prior law, but it has been expanded to include additional organizations who may now donate and distribute under Chapter 709).

28. *See id.* § 15204(g) (amended by Chapter 709) (stating that there are four, rather than three, ways donated medication may be handled).

29. *Id.*; *see also Reverse Distribution Definition*, BUSINESS DICTIONARY, http://www.businessdictionary.com/definition/reverse-distribution.html (last visited Oct. 5, 2012) (on file with the *McGeorge Law Review*) (defining reverse distributor as "collection of damaged, outdated, or unsold goods and bringing them back to the supplier or manufacturer").

30. *See, e.g.*, HEALTH & SAFETY § 150202 (amended by Chapter 709) (increasing the number of facilities that may donate unused medication in a drug repository and redistribution program).

31. *See, e.g.*, E-mail from Dr. George Wang, Co-Founder & Dir., Supporting Initiatives to Redistribute Unused Medication, to author (July 19, 2012, 2:37 PM PST) [hereinafter Wang E-Mail] (on file with the *McGeorge Law Review*) (listing the reasons why SIRUM encouraged expansion of existing law).

32. *Id.* (stating that Chapter 709 allows "more uninsured and underinsured in California to gain access to a larger source of safe, free medicine").

33. E-Mail from Farrah McDaid, Senior Legislative Analyst, Cal. State Ass'n of Cntys., to author (July 10, 2012, 2:16 AM PST) [hereinafter McDaid E-Mail of July 10] (on file with the *McGeorge Law Review*) ("[Chapter 709] allows counties to establish a program simply by majority vote, and we think this will induce

A. *Greater Access for Indigent Patients*

Chapter 709 supporters,[35] including Sierra Club California and California State Association of Counties, hope that the legislation, by easing burdens to participation, donation, and distribution, will help the largest number of people possible.[36] According to Dr. George Wang, Co-Founder and Director of SIRUM, the new law bolsters the "health safety-net for Californians" by "allowing more uninsured and underinsured in California to gain access to a larger source of safe, free medicine."[37] Chapter 709 also has the potential to lower overall healthcare costs in California.[38]

Currently, safety-net clinics, which deliver services to indigent patients regardless of their ability to pay,[39] spend a large amount of money obtaining prescription drugs.[40] Furthermore, underinsured patients who miss doses of required medications frequently require expensive hospitalizations.[41] Chapter 709 not only lowers the procurement costs of medication for safety-net clinics, it could also lead to fewer hospital visits, lessening the burden on the state and taxpayers.[42]

Existing implementations of repository programs have been successful, but only to a limited extent.[43] Of all the counties in California, only Santa Clara and San Mateo have implemented repository and redistribution programs.[44] Also, "hundreds of thousands of dollars['] worth of unused medicine [has] been successfully donated instead of destroyed from a limited pool of eligible donors

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more counties to participate.").

34. Telephone Interview with Annie Pham, Spokesperson, Sierra Club Cal. (July 3, 2012) [hereinafter Pham Telephone Interview] (notes on file with the *McGeorge Law Review*) (describing the environmental effects of unused medication disposed of in a landfill or down the toilet).

35. *See* SENATE RULES COMMITTEE, COMMITTEE ANALYSIS OF SB 1329, at 6–8 (Aug. 25, 2012) (indicating that there is no opposition to Chapter 709 on file).

36. Wang E-Mail, *supra* note 31.

37. *Id.*

38. *Id.*

39. Elizabeth C. Saviano, *California's Safety-Net Clinics: A Primer*, CAL. HEALTHCARE FOUND., http://www.chcf.org/publications/2009/03/californias-safetynet-clinics-a-primer (last visited July 21, 2012) (on file with the *McGeorge Law Review*).

40. *See* Wang E-Mail, *supra* note 31 (stating that drug procurement is the third highest direct cost to safety-net clinics).

41. *See id.* (stating that Chapter 709 could lower patient hospitalizations due to missed doses of necessary medication).

42. *See id.* ("In addition to lowering individual patient costs, passage of SB 1329 will reduce costs for the California healthcare safety net by lowering drug procurement costs of safety-net clinics, currently their third highest direct cost, and lowering patient hospitalizations due to missed doses.").

43. *See id.* (stating the ways in which the two counties that have implemented the program have been successful).

44. *See id.* ("Because this is a new source of medicine, some new processes were developed and fine tuned to efficiently incorporate this program into established work streams.").

and recipient organizations."[45] Supporters hope to build on this success, particularly by making it easier for counties to participate.[46]

B. Expanding County Participation

Many counties have not established drug repository and distribution programs for a number of reasons.[47] First and foremost, law prior to the implementation of Chapter 709 required a county to establish a drug repository and distribution program by ordinance,[48] a process that Farrah McDaid, with the California State Association of Counties (CSAC),[49] characterized as a "time consuming and lengthy process"[50] and that Dr. Wang called "a significant hurdle for implementation."[51] The ordinance process not only involves drafting and vetting the ordinance itself, but also multiple reviews of and public input on the proposed policy.[52] According to Dr. Wang, SIRUM has been working with two counties for more than a year to implement drug repository and distribution programs.[53] CSAC believes that Chapter 709, by allowing implementation by simple majority vote of the county board of supervisors,[54] will lead to greater participation.[55]

CSAC states that the successful implementation of programs in Santa Clara and San Mateo will also influence other counties to establish their own programs.[56] Deborah Pacyna, speaking on behalf of the California Association of

45. *Id.*

46. *See id.* (stating that the requirement that counties implement a program by ordinance has been a challenge; so Chapter 709, by doing away with the ordinance requirement, significantly lowers one hurdle to county participation, making it more likely additional counties will implement programs).

47. *See id.* (explaining that counties implementing programs face "bureaucratic hurdles"); *see also* McDaid E-Mail of July 10, *supra* note 33 (stating reasons why more counties have not established repository and distribution programs under current law).

48. CAL. HEALTH & SAFETY CODE § 150204(a) (West 2012).

49. *See Welcome to CSAC*, CAL. ST. ASS'N OF CNTYS., http://www.csac.counties.org/about-csac (last visited Oct. 5, 2012) (on file with the *McGeorge Law Review*) (stating that the primary purpose of the CSAC is "to represent county government before the California Legislature, administrative agencies and the federal government").

50. E-mail from Farrah McDaid, Senior Legislative Analyst, Cal. State Ass'n of Cntys., to author (Sept. 11, 2012, 11:51 AM PST) [hereinafter McDaid E-Mail of Sept. 11] (on file with the *McGeorge Law Review*) (stating that the ordinance process is lengthier than majority approval because it requires "multiple Board meetings for review and public input" and "significantly more staff time to draft, vet, and pass an ordinance").

51. Wang E-Mail, *supra* note 31.

52. McDaid E-Mail of Sept. 11, *supra* note 50.

53. Wang E-Mail, *supra* note 31.

54. CAL. HEALTH & SAFETY CODE § 150204(a)(1) (amended by Chapter 709).

55. *See* McDaid E-Mail of Sept. 11, *supra* note 50 ("By allowing the Board to decide via majority vote, it makes the establishment of a drug redistribution program a question of county operations, rather than a new policy proposal.").

56. McDaid E-Mail of July 10, *supra* note 33 ("In Santa Clara County, they estimate that the program saves the county $5,000 annually in medication costs for medically indigent adults. This means that the county has saved money while the patient receives needed medication—that is the goal of the program and an example

Health Facilities,[57] agreed, stating that other counties likely took a "wait and see" approach and that a heightened awareness to drug distribution laws in general "made people a bit leery" of the repository and distribution program.[58]

C. Environmental Impact

An environmental impact may be a less-obvious benefit of Chapter 709.[59] "Instead of throwing out perfectly good medication, or worse, dumping it into our water supply, this bill will allow us to get it into the hands of people who need it the most," said Senator Joe Simitian.[60]

Annie Pham, spokesperson for the Sierra Club California, says medical waste is toxic to wildlife and fish and has been a growing problem.[61] Currently, there is no infrastructure in place for pharmaceutical waste management.[62] Until there is a management solution in place, Ms. Pham says efforts to keep medication out of the environment are the best option.[63]

Although two counties have successfully implemented drug repository and redistribution programs, potentially providing some insight into the environmental success of the original legislation, there is no conclusive information available on this point.[64] According to Ms. Pham, because counties establish drug repository and distribution programs, Sierra Club California does not know whether there has been a positive environmental impact.[65]

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of success. If SB 1329 passes, we feel that more counties will establish such programs.").

57. *See About CAHF*, CAL. ASS'N OF HEALTH FACILITIES, http://cahf.org/About CAHF.aspx (last visited Oct. 5, 2012) (on file with the *McGeorge Law Review*) (describing CAHF as "dedicated to improving the quality of long-term health care in California through educational programs and proactive advocacy with the Legislature and administrative agencies").

58. Telephone Interview with Deborah Pacyna, Spokesperson, Cal. Ass'n of Health Facilities (July 3, 2012) [hereinafter Pacyna Telephone Interview] (notes on file with the *McGeorge Law Review*).

59. *See* Press Release, State Senator Joe Simitian, The Right Medicine for California: Simitian Introduces Drug Redistribution Bill to Reduce Waste, Improve Health (Feb. 24, 2012) (on file with the *McGeorge Law Review*) (stating that Chapter 709 will help prevent environmental waste and pollution).

60. *Id.*

61. Pham Telephone Interview, *supra* note 34 (stating that drug interaction from medications that end up in streams and rivers has been associated with feminizing male fish, although Sierra Club California has not performed independent studies).

62. *Id.*

63. *Id.*

64. *Id.*

65. *Id.* However, consumers with extra medication typically dispose of it by flushing it down the toilet or throwing it in the trash. CHRISTIAN G. DAUGHTON, U.S. EVTL. PROTECTION AGENCY, DRUGS AND THE ENVIRONMENT: STEWARDSHIP & SUSTAINABILITY 13 (2010), *available at* http://www.epa.gov/esd/bios/daughton/APM200-2010.pdf (on file with the *McGeorge Law Review*). This, "unfortunately[,] can add to the overall level of pharmaceutical pollutants in the environment (by way of treated wastewater or sludge)." *Id.* Therefore, to the extent that individuals—rather than organizations—dispose of medications, environmental impact will likely continue to be a problem. *Id.*

V. CONCLUSION

Chapter 709 makes it easier for counties to establish drug repository and distribution programs.[66] Chapter 709 also increases the number of facilities authorized to donate medication, as well as receive and redistribute medication to indigent patients.[67] The successful implementation of the programs in counties prior to Chapter 709's enactment decreases the uncertainty that accompanied the 2005 legislation.[68] However, a question does remain: will Chapter 709, in lowering bureaucratic hurdles, actually lead to a greater number of programs?[69] Supporters believe it will, particularly because San Mateo and Santa Clara provide good examples of functioning programs.[70] Increasing the number of programs in existence, as well as the number of facilities that may donate and distribute, is critical to the ultimate goal behind Chapter 709: helping the greatest number of people possible.[71]

66. CAL. HEALTH & SAFETY CODE § 150204(a)(1) (amended by Chapter 709) (stating that county board of supervisors or public health officers may establish drug repository and distribution programs, when, previously, an ordinance was the only method for establishing a program).

67. *Id.* §§ 150201, 150202(a) (amended by Chapter 709).

68. *See* ASSEMBLY COMMITTEE ON HEALTH, COMMITTEE ANALYSIS OF SB 1329, at 4 (June 19, 2012) (discussing that Santa Clara and San Mateo have not experienced any problems after establishing drug repository and distribution programs).

69. *See* Wang E-Mail, *supra* note 31 (stating that two additional counties, Sonoma and Riverside, have already expressed interest in creating repository and redistribution programs).

70. Pacyna Telephone Interview, *supra* note 58.

71. Wang E-Mail, *supra* note 31.