

The Effects of Medicare's Donut Hole and
Congress's Solution

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I. INTRODUCTION

In 2006, the Medicare Prescription Drug, Improvement and Modernization Act (MMA) created Medicare Part D to aid senior citizens and the disabled with their ever-increasing prescription drug bills. This plan was controversial from the time of its enactment. Left leaning policy makers believed that the MMA did not provide enough coverage for seniors,¹ while those on the right thought the plan did little to help reform the system and viewed it as a “blank check from the government.”² Although Part D provided coverage to those previously without it, it has forced some people to make difficult choices between whether to purchase their medication or spend that money on other essentials, such as rent and electricity.³ Many Part D beneficiaries were unaware that when their prescription costs reached \$2,830 in 2010, the monetary limit, they entered a coverage gap known as the “donut hole.”⁴ This means that once a beneficiary and Medicare combine to pay \$2,830 on prescription drugs, the beneficiary is then responsible for 100 percent of the next \$3,610 of prescription costs.⁵ Once beneficiaries

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1. Susan Adler Channick, *The Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Will it be Good Medicine for U.S Health Policy*, 14, ELDER L.J. 237, 240 (2006).

2. *Id.*

3. *Filling the Medicare 'doughnut hole'*, VIEWPOINT: CONSUMER REP. (Nov. 2006), <http://www.consumerreports.org/cro/aboutus/mission/viewpoint/medicare-drug-plan-11-06/overview>.

4. Christopher Weaver, *Healthcare plan closes the Medicare 'doughnut hole'*, L.A. TIMES, Mar. 26, 2010, <http://articles.latimes.com/2010/mar/26/health/la-he-healthcare-doughnut-20100323/3>; 42 C.F.R. § 423.104 (2010).

5. Weaver, *supra* note 4 at 1.

reach the threshold of \$6,440, Medicare's "catastrophic coverage" kicks in, and the beneficiary is then responsible for just 5 percent of their drug expenses out-of-pocket.⁶ Congress created the donut hole because it was the only way to finance the prescription drug plan⁷ and to encourage its beneficiaries to use their drugs more judiciously.⁸ However, despite Part D's laudable intentions, this created many problems for Medicare and its beneficiaries.

This changed in March 2010, when Congress included a provision in the Health Care and Education Reconciliation Act that ends the coverage gap beginning in 2020.⁹ Although there will continue to be a hole in coverage for the next ten years, Congress has taken several steps to ease some of the immediate financial burdens, which beneficiaries must seek out via alternative assistance. This article will first discuss some of the challenges associated with the coverage gap. Next, it will analyze Congress' latest plan as part of healthcare reform to permanently close the donut hole. Finally, it discusses some of the alternative methods proposed for Medicare patients to help ease the burden imposed by the donut hole before the healthcare reform changes go into effect in 2020.

II. DISCUSSION OF PRESCRIPTION DRUG COVERAGE ISSUES

Some Part D beneficiaries are forced to forego their medications when they reach the donut hole.¹⁰ This problem is especially prevalent for patients with chronic illnesses, as demonstrated in a 2008 study where 15 percent of those with chronic illnesses stopped purchasing, and taking, their medications when they hit the donut hole.¹¹

6. *Id.*; see also *Medicare Resource Center*, EHEALTH MEDICARE, <http://www.ehealthinsurance.com/medicare-insurance/plans/part-d/#> (last visited Jan. 20, 2011) ("Catastrophic Coverage assures that once a person has spent up to the plan's out-of-pocket limit for covered drugs, he or she will only pay a small co-insurance amount or a co-payment for the rest of the year.").

7. Arlene Weintraub, *Health Benefits: Medicare's Costly Doughnut Hole*, BLOOMBERG BUS. WK., (Oct. 15, 2008), http://www.businessweek.com/bwdaily/dnflash/content/oct2008/db20081010_836793.htm.

8. *Medicare Recipients in 'Doughnut Hole' Skip Meds*, CONSUMER AFF. (Jan. 8, 2010), http://www.consumeraffairs.com/news04/2010/01/doughnut_hole.html.

9. Health Care and Education Reconciliation Act of 2010 ("HCREA"), Pub. L. No. 11-152, 124 Stat. § 1101 (2010).

10. Weintraub, *supra* note 7, at 1.

11. *Id.*

Understandably, the study cited high drug costs as the reason Part D beneficiaries stopped taking their medications when they were in the coverage gap.¹²

A recent UCLA study conducted by Dr. Vicki Fung from Kaiser Permanente and the David Geffen School of Medicine at UCLA sheds additional light on this issue.¹³ The study traced the adherence rate (the rate at which patients continued to take their medications) of beneficiaries when they reached the donut hole,¹⁴ and analyzed whether the participants stopped taking their medications once they were responsible for the total cost.¹⁵ The results showed that the coverage gap produced cost savings in the aggregate, but also resulted in many unfilled prescriptions.¹⁶ In effect, once some beneficiaries were in the donut hole, they did not continue to take their medications.¹⁷ Although it realized an initial cost savings, studies show the impact on adherence rates may have a detrimental impact on beneficiaries' health, which may erase any initial cost savings in the long term.

A. Patients Who Stop Taking Their Medications Lead to Preventable Hospitalizations

Again, a lack of coverage created by the donut hole causes some beneficiaries to either switch or completely forego their medications.¹⁸ Generally, without financial assistance for their prescriptions, patients are often forced to go without necessary medication, take less than the necessary dosage, or neglect their basic needs.¹⁹ Forgoing medication can lead to the development of additional health concerns in patients whose conditions were controlled while medicated.²⁰ This is especially true for diabetes mellitus patients, 75

12. *Id.*

13. *Medicare Recipients in 'Doughnut Hole' Skip Meds*, *supra* note 8, at 1.

14. *Id.*

15. *Id.*

16. *Id.*

17. *Id.*

18. Robert Preidt, *3.4 Million Seniors Hit Medicare 'Doughnut Hole': In many cases, enrollees stop taking meds as they reach this coverage gap*, ABC NEWS (Aug. 22, 2008), <http://abcnews.go.com/Health/Healthday/story?id=5630442&page=1>

19. *Filling the Medicare 'doughnut hole'*, *supra* note 1, at 1.

20. *See generally*, Mollie Ashe Scott et al., *Hospital admission associated with Medicare Part D "doughnut hole,"* 64 AM. J. HEALTH-SYS. PHARM.. 1029, 1029 (2007).

percent of whom will fall into the donut hole.²¹ For example, one such patient, a 76 year old woman, effectively managed her diabetes while on medication, but after the donut hole cut off her coverage, she changed her medication because it became too costly.²² Ten days later, she was admitted to the hospital.²³ This demonstrates a larger problem – when patients are forced to switch their medications, or forgo them all together, the results can be costly in both health and financial terms. At a most basic level, a change in medication can increase the risk of falling seriously ill for many beneficiaries whose dosage previously controlled their condition.

As such, closing the donut hole could ease the financial burden on Medicare by reducing preventable hospitalizations.²⁴ When seniors are forced to choose between their prescription drugs and other necessities, adherence studies show that some choose other necessities.²⁵ Studies show that when claimants enter the donut hole they reduce their medication intake by 187 days of treatment or by approximately 14 percent.²⁶ The diabetes mellitus example above illustrates this well. Instead of Medicare Part D decreasing costs, it actually increased long-term costs for the system due to preventable hospitalization.²⁷ Therefore, even though the purpose of Medicare Part D was to make prescription drugs more affordable for seniors, it is not solving the problem for those who find themselves in the donut hole.

III. THE HEALTH CARE REFORM BILL AND THE CLOSING OF THE DONUT HOLE

The Health Care and Education Reconciliation Act (HCEA) put to rest the uncertainty surrounding the future of Part D and its donut hole. The HCEA is the second of two

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.*

25. *Medicare Recipients in 'Doughnut Hole' Skip Meds*, *supra* note 8, at 1.

26. Michael H. Kim et al., *National Assessment of Medicare Prescription Plan Coverage Gaps Among Patients with Atrial Fibrillation in the US*, SPRINGER HEALTHCARE 784,792 (2009).

27. Scott, *supra* note 20, at 1029.

healthcare reform bills passed in 2010, commonly known as the reconciliation bill.²⁸ It also increased the tax credits for middle income families who choose to purchase insurance, lowered the penalty levied for individuals who do not purchase insurance, required that doctors who accept Medicaid be repaid at the full rate, imposed a Medicare tax on unearned income for families over \$250,000, and implemented several student loan reform provisions.²⁹ However, the highlight of this bill for those on Medicare's Part D prescription drug plan was the provision that called for the close of the donut hole by 2020 as mentioned in Section 1101 of the bill.³⁰

A. The HCEA's Donut Hole Provision

To help offset the cost of drugs in 2010, Congress issued \$250 checks to any beneficiary in the senior that entered the donut hole.³¹ Beginning in 2011—when beneficiaries hit the coverage gap—they will be responsible for 50 percent of their prescription payments, with additional incentives phased in until the gap is closed in 2020, and beneficiaries will only be responsible for 20 percent of their prescription costs.³² Although these measures will certainly help, they do not solve the problem.³³ Luckily, there are other options to help lower prescription costs.³⁴ Such alternatives include: the use of generic drugs, state prescription plans, and pharmaceutical discount programs that, if implemented and used properly, could help seniors until the gap is finally closed.³⁵

Between 2010 and 2020, the government will provide aid to those in the donut hole

28. See *Breaking—Reconciliation Bill Posted*, POLITICO.COM http://www.politico.com/livepulse/0310/BREAKING__Reconciliation_bill_posted_.html (last visited, Apr. 6, 2011).

29. *Id.*

30. *Id.*

31. Patricia Murphy, *\$250 'Donut Hole' Check Is in the Mail for Seniors' Drugs*, POL. DAILY (Jun. 11, 2010), <http://www.politicsdaily.com/2010/06/11/250-donut-hole-check-is-in-the-mail-for-seniors-drugs/>; Health Care and Education Reconciliation Act of 2010, *supra* note 9, at § 1101.

32. *Id.*

33. *Id.*

34. See Janna M. Pulver, *Pharmaceuticals and Medical Devices: Cost Savings*, HEALTH POL. TRACKING SERV. - ISSUE BRIEFS, July 12, 2010, at 1.

35. See generally *id.*

until it is effectively closed.³⁶ The government has tried to offset the cost for those who reach the coverage gap in 2010 by offering them \$250.³⁷ Projected federal costs for this remedy, which an estimated that four million people utilize, arrive at roughly one billion dollars.³⁸ This costly expenditure will last just one year. After 2010, beneficiaries in the donut hole will receive discounts instead of a reimbursement check,³⁹ with beneficiaries paying 50 percent of prescription costs out of pocket instead of the current 100 percent.⁴⁰

In addition, drug companies have agreed to offer a 50 percent discount on prescriptions filled to beneficiaries in the donut hole.⁴¹ The government will not bear responsibility for these discounts, however, as they are being offered by the pharmaceutical companies themselves.⁴² The pharmaceutical companies agreed to this discount because it will drive continued sales of pharmaceuticals, as more beneficiaries will actually fill prescriptions than when no discount was given.⁴³ In fact, one analyst stated that "Because of the discounts. . . Medicare beneficiaries are likely to continue filling prescriptions in the donut hole, whereas in the past many stopped taking their medications because the drugs were unaffordable to them."⁴⁴ President Obama called this deal a "significant breakthrough on the road to healthcare reform."⁴⁵ In sum, a patient who would normally need to pay for 100 percent of their medications will now be receiving a 50 percent discount, which should significantly reduce their burden.⁴⁶ Finally, the healthcare system benefits because this initiative saves the health care system

36. BENJAMIN HUNT & KAREN DAVENPORT, CTR. FOR AM. PROGRESS, *THE AFFORDABLE CARE ACT'S REPEAL WOULD LEAVE THE DOUGHNUT HOLE OPEN 2* (2008).

37. Health Care and Education Reconciliation Act of 2010, *supra* note 9, at § 1101.

38. Murphy, *supra* note 31, at 1.

39. *Id.*

40. Health Care and Education Reconciliation Act of 2010, *supra* note 9, at § 1101.

41. Robert Pear, *Federal Saving From Lowering of Drug Prices Is Unclear*, N.Y. TIMES, Jun. 23, 2009, <http://www.nytimes.com/2009/06/23/health/policy/23health.html>.

42. *Id.*

43. *Id.*

44. *Id.* (emphasis omitted).

45. *Id.*

46. *Id.*

\$80 billion over next ten years by lowering the cost of prescription drugs.⁴⁷

B. Positive Reviews for HCEA's Donut Hole Provision

HCEA's closing of the donut hole by 2020 has received many positive reviews.⁴⁸ The AARP was satisfied with the bill, citing concerns for the rising costs of prescription drugs.⁴⁹ The AARP supported the bill soon after its passage, and commended Congress for finally beginning the process of closing the donut hole.⁵⁰ Barry Rand, the AARP's top executive stated, "With the cost of prescription drugs continuing to skyrocket, closing the 'donut hole' will help millions of older Americans afford their needed medications and avoid more intensive and costly care later in life."⁵¹ In particular, Democratic lawmakers have been using the Medicare Part D provision to help gain support for all of the reforms.⁵² Representative Lucille Roybal-Allard explained this well, saying, "Who among us will not be more secure knowing that our parents will be protected from the Medicare Part D 'donut hole' which has made life-saving medications so unaffordable for those that need them most?"⁵³ Even Republican lawmakers supported the "expansion of prescription drug coverage for elderly."⁵⁴ Evidently, despite health care reform's lack of bipartisan support, the closing of the donut hole received widespread support.⁵⁵ Nevertheless, because it will not be closed until 2020, an analysis of beneficiaries' immediate remedies is necessary.

47. *Id.*

48. *AARP: Reform should end 'doughnut hole'*, UPI (Mar. 22, 2010, 1:31 AM), http://www.upi.com/Health_News/2010/03/22/AARP-Reform-should-end-doughnut-hole/UPI-88881269235891/; Stacy Johnson, *Health Care Reform: 8 Positive Changes*, MONEY TALKSNEWS, Mar. 22, 2010, <http://www.moneytalksnews.com/2010/03/22/health-care-reform-8-positive-changes/>; Alan Flaumenhaft, *Health Care Reform has Many Positive Provisions for the Disability Community We Serve*, FREEDOM DISABILITY, APR. 21, 2010, <http://www.freedomdisability.com/health-care-reform-for-the-disabled/>.

49. *AARP: Reform should end 'doughnut hole'*, *supra* note 48.

50. *Id.*

51. Weaver, *supra* note 4, at 2.

52. *Id.* at 1.

53. *Id.*

54. Adam Nagourney, *Republicans Face Drawbacks of United Stand on Health Bill*, N.Y. TIMES, Mar. 22, 2010, <http://www.nytimes.com/2010/03/23/us/politics/23repubs.html>.

55. *Id.*

IV. REMEDIES AVAILABLE BEFORE 2020

Prior to the donut hole closing in 2020 beneficiaries will have options to help lower their costs when they reach the donut hole, or prevent them from getting there in the first place. With the aid of Congress and the drug companies, there are plans in place over the next ten years to help offset some of the costs associated with the donut hole.⁵⁶ Also, increasing the use of generic drugs, which are much more affordable, will make it more difficult to enter the donut hole, and make it less expensive for those who end up there.⁵⁷ Finally, some states have their own plans that work together with the federal program to help beneficiaries with high prescription drug costs.⁵⁸

A. The Use of Generic Drugs to Lower Costs

One way to lower the cost of prescription drugs is to switch patients to generic drugs.⁵⁹ Generic drugs are copies of name brand drugs with expired patents. They use the same active ingredient, offer the same benefits of name brand drugs, are as safe as the name brand drugs, and undergo the same stringent testing under the FDA as their brand name counterparts.⁶⁰ Currently, 80 percent of name brand drugs have substantially cheaper generic counterparts.⁶¹ A 2006 study showed that a drug like Nexium costs \$179 a month, while Prilosec OTC, a generic counterpart that treats the same symptoms with equal effectiveness only costs between \$12 and \$24.⁶² Use of generic drugs may be beneficial for patients because generics are often as effective as brand-name drugs, but cost significantly less.

Generic counterparts are not available for all name brand drugs because of the United

56. Pear, *supra* note 41; Murphy, *supra* note 31.

57. See Pulver, *supra* note 34 at 1.

58. See *id.*

59. *Shoppers Guide To Prescription Drugs –Number 2: Generic Drugs*, CONSUMER REP. 1 (2006), <http://www.consumerreports.org/health/resources/pdf/best-buy-drugs/money-saving-guides/english/GenericDrugs-FINAL.pdf> [hereinafter *Shoppers Guide To Prescription Drugs*].

60. *Id.* at 1

61. JANET LUNDY, KAISER FAMILY FOUND., *PRESCRIPTION DRUG TRENDS*, 4 (May, 2010), www.kff.org/rxdrugs/upload/3057-08.pdf.

62. Matthew Perrone, *Smart Rx: Drugs that Work and Won't Break the Bank*, ASSOCIATED PRESS, Nov. 4, 2009, available at <http://abcnews.go.com/Health/wireStory?id=8995861>.

States patent process, which provides a rigid framework for generic market entry.⁶³ In most cases once a drug is patented, the manufacturer has the exclusive right to sell the drug on the open market for 20 years.⁶⁴ Thus, a pharmaceutical company will charge the highest price possible for a patented drug because their profit-window is limited.⁶⁵ It commonly takes ten years for the drug to reach the open market following its discovery and subsequent patent.⁶⁶ Therefore, approximately half of the pharmaceutical companies exclusive marketing rights are gone before the drug hits the market.⁶⁷ Further, drug companies argue that they need this exclusive window to help pay for the research and development costs associated with the drugs.⁶⁸

Recent studies have shown that the increased use of generic drugs impacted the amount of money patients spent on them.⁶⁹ One such study done by the AARP Public Policy Institute highlighted how generic drugs affected the market for all prescription drugs.⁷⁰ The study focused on how the introduction of more generic drugs into the market reduced drug inflation, making it easier for consumers to purchase the drugs that they need at affordable prices.⁷¹ The study showed that when generics entered the market, prices began to fall.⁷² The introduction of the second generic into the marketplace had the greatest impact on the drugs price.⁷³ An FDA study showed that

63. *Id.*

64. *Id.*

65. *Id.*

66. Harold M. Silverman, *Trade Name and Generic Drugs*, MERCK MANUAL, APR. 2007, <http://www.merckmanuals.com/home/sec02/ch017/ch017a.html>

67. *Id.*

68. Mark Weisbot, *Drug Patent Rules Must Allow Exceptions for Public Health*, CTR. FOR ECON. & POLICY RES., Mar.12, 2008, <http://www.cepr.net/index.php/op-eds-&-columns/op-eds-&-columns/drug-patent-rules-must-allow-exceptions-for-public-health>

69. DAVID J. GOSS, ET AL., AARP PUBLIC POLICY INSTITUTE, RX WATCHDOG REPORT: TRENDS IN MANUFACTURER PRICES OF GENERIC PRESCRIPTION DRUGS USED BY MEDICARE BENEFICIARIES 2003 TO 2007, 19 (2008).

70. *Id.*

71. *Id.*

72. *Id.*

73. *Generic Competition and Drug Prices*, (U.S FOOD AND DRUG ADMINISTRATION FDA, 2005), available at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm> (last updated Mar. 1, 2010)..

introducing generics into the marketplace caused a price reduction to half of the brand name drug.⁷⁴ By switching to generic variants, those who lack insurance coverage will be able to reduce their economic strain.⁷⁵

B. The Use of SPAP Programs to Help Lower Costs

Another place Medicare Part D beneficiaries can receive aid from is through a State Pharmaceutical Assistance Program (SPAP).⁷⁶ In fact, many states had prescription drug programs in place prior to the MMA.⁷⁷ Due to the donut hole in Part D coverage, some states have used their SPAP programs to address this problem.⁷⁸ These programs, called “Wrap Around” programs fill the gaps left by the federal program, and provide coverage where it is needed.⁷⁹ Wrap Around coverage allows “for combining a set of federally-funded benefits with another package of state-funded benefits, enabling the enrollee to pay lower out-of-pocket charges for prescriptions than with the federal program alone, or to receive a type of drug not available through Medicare.”⁸⁰ Today, there are thirty-eight states that offer some sort of SPAP program.⁸¹

While SPAP programs differ from state to state, those that offer Wrap Around benefits have several common elements.⁸² Many include the state covering some or all of Part D beneficiaries’ deductibles and monthly premiums.⁸³ Others include co-payments, donut hole coverage, and drugs that are not covered by the Part D drug plan.⁸⁴ Most of these

74. *Id.*

75. *Shoppers Guide To Prescription Drugs*, *supra* note 59, at 2.

76. *State Pharmaceutical Assistance “Wrap Around” Programs: Helping to Make Medicare Part D Easier and More Affordable*, NAT’L CONF. OF ST. LEG. (Mar. 2010), <http://www.ncsl.org/Default.aspx?TabId=14395> [hereinafter *State Pharmaceutical Assistance “Wrap Around” Programs*].

77. *State Pharmaceutical Assistance Programs*, NAT’L CONF. OF ST. LEG. (May, 2010), <http://www.ncsl.org/default.aspx?tabid=14334> [hereinafter *State Pharmaceutical Assistance Programs*].

78. Pulver, *supra* note 34, at 13

79. *State Pharmaceutical Assistance “Wrap Around” Programs*, *supra* note 76, at 1.

80. *Id.*

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.*

plans require enrollment in the Part D program as a condition to get these benefits.⁸⁵ Each state's Wrap Around program offers different benefits.⁸⁶ For example, the Illinois program has benefits that include payment of: all deductibles and premiums associated with Part D and 25 percent of the cost of prescriptions while in the donut hole.⁸⁷ This program also covers some drugs that are not covered by Medicare such as benzodiazepines.⁸⁸ Delaware and Indiana have similar programs, while states such as Kansas and Montana have less extensive plans.⁸⁹ Overall, State Wrap Around programs are a way for many seniors to help offset the costs associated with Medicare's Part D prescription plan, especially once they reach the donut hole.⁹⁰ However, these plans cannot be a solution for everyone since not every state has these benefits, and some states offer more benefits than others.

V. CONCLUSION

Medicare Part D and the donut hole have created quite a stir over the past four years. However, with the help of the HCEA, the severity of the problem has been significantly lessened. Although adherence issues for beneficiaries in the donut hole have caused problems for both beneficiaries and hospitals, the eventual closing of the donut hole could positively impact many people's lives. However, the donut hole will not be closed until 2020, so alternatives such as a greater reliance on generic drugs and enrollment in state wrap around programs are necessary to help ease the burden until the full financial benefits of the reform bill can be felt. At some level though, the onus remains on the beneficiaries to help themselves until the full effect of the bill takes effect.

85. *Id.*

86. *State Pharmaceutical Assistance Programs, supra note 77, at 1.*

87. *Id.*

88. *Id.*

89. *Id.* at 8, 11, 12, 16.1.

90. *See generally, id.* at 1.