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## HOW STATES CAN PROMOTE HEALTH CARE ACCESS AND AFFORDABILITY WHILE ENHANCING PATIENT AUTONOMY

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### INTRODUCTION

The state of health care in America suffers no shortage of critics. The perennial issues of access and affordability have forced every president (and presidential candidate) to detail their solutions in front of the watching populace. The issues are bipartisan, but often the proposed solutions are not.<sup>1</sup> However, both sides of the aisle aim to lower prescription drug prices largely through central planning. Yet, these proposals are controversial and may have detrimental, unintended consequences.<sup>2</sup>

The debate over how best to lower prescription drug prices is expected to continue, but it remains focused on only one

component of the problem. Many of these proposals miss that the total cost of a prescription is not just monetary: visits to the doctor's office to get a prescription add a significant time and financial cost to patients. Reducing the need for these costly visits can provide relief to patients and lower the overall cost of access to health care. It can also increase their access to and utilization of therapies, especially by those with fewer economic resources who might otherwise forgo treatment.

Fortunately, there are free market-oriented, scope-of-practice solutions that increase affordability by expanding access. Further, these solutions can occur on the state level with bipartisan support. For example, states are beginning to expand the scopes of practice for highly skilled medical professionals like pharmacists and nurse practitioners as a way to increase access to services and lower the overall costs incurred. However, in many states, there is much more

1. Sarah Karlin-Smith, "How Trump and the Democrats parted ways on lowering drug prices," *Politico*, Dec. 11, 2019. <https://www.politico.com/news/2019/12/11/donald-trump-democrats-drug-pricing-082545>.

2. See, e.g., Wall Street Journal Editorial Board, "Trump's Drug Price Panic," *The Wall Street Journal*, July 26, 2020. <https://www.wsj.com/articles/trumps-drug-price-panic-11595798381>.

to be done on this front: pharmacists' scope of practice can be expanded to further improve access and affordability in health care—all without waiting on federal action.

## HISTORICAL BACKGROUND

### Pure Food and Drug Act of 1906

In reaction to highly publicized instances of consumers being defrauded, misled or even poisoned by manufactured drugs, Congress passed the Pure Food and Drug Act in 1906. The law codified the privately created United States Pharmacopoeia (USP) and defined a drug as “adulterated” if it failed to meet USP specifications.<sup>3</sup> The USP is a voluntary organization, founded in 1820, that maintains a compendium of standards for “quality, purity, strength, and identity standards for medicines, food ingredients, and dietary supplements.”<sup>4</sup>

This in and of itself did not change things substantially because the USP was already the widely recognized standard of practice. However, the law introduced the crime of “misbranding.”<sup>5</sup> A drug was considered misbranded if it contained alcohol, opium, cocaine or any other dangerous or potentially addictive substance and failed to list those ingredients and their proportional inclusion on the product label.<sup>6</sup> The Act did not in any way infringe on the right to self-medication, but rather provided consumers with more information. The Bureau of Chemistry was empowered to administer the new law, but it was not empowered to determine the efficacy of a product. However, the Sherley Amendment of 1912 allowed for prosecution if a manufacturer knowingly made false or fraudulent claims about a drug.<sup>7</sup> In 1927, the Bureau of Chemistry was reorganized into the Food, Drug and Insecticide Administration, and renamed the Food and Drug Administration (FDA) in 1930.<sup>8</sup>

### Food, Drug and Cosmetic Act of 1938

In 1938, another highly publicized event spurred new legislation. To ease oral administration, the Massengill Company released a new formulation of their antibiotic sulfanilamide—which was already successfully used and manufactured—as an elixir. While the drug was made according to specifications, alcohol was not the solvent used, and therefore it did

not meet the standard for branding as an elixir. Instead, the solvent diethylene glycol—known today as antifreeze—was used. This resulted in 107 poisoning deaths, mostly of children, before the product was recalled.<sup>9</sup> The Massengill Company was guilty of misbranding under the Pure Food and Drugs Act, and was successfully sued in court for gross negligence.<sup>10</sup> Nevertheless, Congress saw the need to pass new legislation.

In 1938, Congress passed the Food, Drug and Cosmetic Act (FD&C). Among its key provisions was the requirement that manufacturers file a New Drug Application (NDA)—which included the drug's composition, safety test results and information on how its manufacture would be controlled for quality—to the FDA before they could market any new drug.<sup>11</sup> Drugs already on the market with a record of proven safety were not affected. If the FDA failed to act within 60 days of the application submission, the drug would be automatically approved.<sup>12</sup> The law also expanded misbranding criteria. It required drug manufactures to list all ingredients on the label, not just the dangerous ingredients, in their precise amounts. In addition, it required the labels to list effects, possible side effects and instructions for use—including cautionary instructions—that the least-educated person could understand.<sup>13</sup>

Prior to the FD&C, manufacturers decided whether to market their drug over-the-counter (OTC) or by prescription only. Often, they would make this determination based upon liability and other considerations. For example, some manufactures learned they were able to get higher profits if their product was sold as prescription-only.<sup>14</sup> As a result, some manufacturers would market a drug only through a prescription while others would market that same drug OTC. The 1938 law promoted the idea of prescription-only drugs as it allowed manufacturers to avoid the requirement that their label be understood by the least-educated consumer if the label read: “Caution: To be used only by or on the prescription of a physician.”<sup>15</sup> In that case, the sale of the product OTC would be illegal. Still, the intent of the law was to provide consumers with information, not to infringe on the right of self-medication. In fact, the House committee that reported the bill stated: “[This] bill is not intended to restrict

3. “History of Federal Regulation: 1902-Present,” The Independent Institute, last accessed Sept. 24, 2020. <https://www.fda.gov/oc/ohrt/history-of-federal-regulation-1902-present/#p06>.

4. “What is the U.S. Pharmacopeia?” The United States Pharmacopeia, Aug. 4, 2015. <https://qualitymatters.usp.org/what-us-pharmacopeia>.

5. “History of Federal Regulation: 1902-Present.” <https://www.fda.gov/oc/ohrt/history-of-federal-regulation-1902-present/#p06>.

6. Ibid.

7. Ibid.

8. Ibid.

9. Ibid.

10. Ibid.

11. Ibid.

12. Ibid.

13. Ibid.

14. Gregory W. Reilly, “The FDA and Plan B: The Legislative History of the Durham-Humphrey Amendments and the Consideration of Social Harms in the Rx-OTC Switch,” The Harvard Law School, May 12, 2006. <https://dash.harvard.edu/bitstream/handle/1/8965550/Reilly06.html?sequence=2>.

15. “History of Federal Regulation: 1902-Present.” <https://www.fda.gov/oc/ohrt/history-of-federal-regulation-1902-present/#p06>.

in any way the availability of drugs for self-medication. On the contrary, it is intended to make self-medication safer and more effective.”<sup>16</sup>

Therefore, the FD&C intended for patients to routinely seek the expert advice of doctors and dentists and receive recommendations and prescriptions. They could then weigh those recommendations with other inputs, including the insights and recommendations of pharmacists. But in the end, the patients themselves would decide what advice to follow and what medications to self-administer.

### Durham-Humphrey Amendment of 1951

Respect for the right to self-medicate, at least in principle, ended abruptly with the passage of the Durham-Humphrey Amendment in 1951. The amendment authorized the FDA to classify drugs as either OTC or prescription-only.<sup>17</sup> Prescription-only drugs were only allowed to be sold to people presenting a prescription from a health care practitioner licensed by a state. In addition, the prescription-only classification was no longer left to the discretion of manufacturers. Instead, the FDA commissioner was empowered to determine a drug’s classification as an additional consideration when reviewing an NDA. This had the effect of institutionalizing health care practitioners’ control and authority over the medication decisions of individuals. It also added to health care costs by requiring visits to the doctor’s office to obtain a prescription.

The Durham-Humphrey Amendment was supported by the pharmacy profession; and its two authors, Rep. Carl Durham (D-NC) and Sen. Hubert Humphrey (D-MN), were pharmacists before entering politics. The goal of the amendment was to eliminate the lack of uniform drug classification among the various manufacturers, which often led to confusion and liability concerns for pharmacists.<sup>18</sup> It also allowed for prescriptions with authorized refills—prescriptions had previously been single-use only—and allowed doctors to phone-in prescriptions if the they were immediately converted to one in writing. Additionally, it established rules and procedures for switching a drug’s classification from prescription-only to OTC.<sup>19</sup> The amendment exempted drugs already on the market that had a proven record of safety. This is why a few of the original brands of insulin extracted from agricultural animals (e.g., Humulin and Novo-Novolin), already on the

market prior to the 1938 FD&C are still available in most states without a prescription.<sup>20</sup>

### INTERNATIONAL VARIATIONS IN PRESCRIPTION POLICIES

The American pharmaceutical regulatory regime serves as the model for much of the developed world. For example, most developed countries have agencies that are analogous to the FDA which determine the drugs that may enter the market, as well as any prescription requirements. Yet, the model is unevenly applied in regions of the world that have adopted its template. Many countries that officially follow the Durham-Humphrey model enforce it only weakly, with pharmacies ignoring the regulations and selling directly to self-medicating consumers. Poor compliance with prescription drug laws has been documented in India, Hong Kong, Colombia, Peru and numerous other countries.<sup>21</sup> Mexico, for example, only requires prescriptions for antibiotics and controlled narcotics, but compliance with prescription requirements for antibiotics has been inadequate.<sup>22</sup>

Numerous drugs that may be obtained OTC for self-medication in other countries require a prescription in the United States. This means that regulatory agencies in other countries have come to different conclusions regarding the potential for harm posed by certain drugs. A few examples of these differences are as follows:

- Simvastatin (cholesterol-lowering drug) does not require a prescription in the United Kingdom.<sup>23</sup>
- Short-acting hormonal contraceptive methods are available either de facto OTC or officially OTC in the majority of countries.<sup>24</sup>

20. See, e.g., Jim Cahill, “Why is Some Insulin Available Over the Counter?” *Insulin Nation*, July 12, 2017. <http://insulinnation.com/treatment/why-is-some-insulin-available-over-the-counter>; Sarah Jane Tribble, “You Can Buy Insulin Without A Prescription, But Should You?,” *NPR*, Dec. 14, 2015. <https://www.npr.org/sections/health-shots/2015/12/14/459047328/you-can-buy-insulin-without-a-prescription-but-should-you>.

21. See, e.g., Sushmi Dey, “Soon, Centre to add 100 more drugs to over-the-counter list,” *The Times of India*, Sept. 22, 2017. <https://timesofindia.indiatimes.com/india/soon-centre-to-add-100-more-drugs-to-over-the-counter-list/articleshow/60787958.cms>; Natasha Fernandes, “Illegal sale of antibiotics still common in Hong Kong,” *HKU Journalism*, March 20, 2017. <https://jmhc.hku.hk/reportinghealth2016/2017/03/17/illegal-sale-of-antibiotics-still-common-in-hong-kong>; Claudia Patricia Vacca et al., “Restriction of antibiotic sales in pharmacies in Bogota, Colombia: a descriptive study,” *Pan American Journal of Public Health* 30:6 (December 2011), pp. 586-591. <https://www.ncbi.nlm.nih.gov/pubmed/22358407>; “Farmacias,” *Peru Explorer*, last accessed Sept. 24, 2020. <https://www.peru-explorer.com/farmacias.htm>; Sam Peltzman, “By Prescription Only...or Occasionally?” *Regulation* 11 (1987), pp. 23-28. <https://object.cato.org/sites/cato.org/files/serials/files/regulation/1987/12/v11n3-4-4.pdf>.

22. Mikel Andoni Arriola-Peñalosa, “The role of health regulations in the rational use of medicines,” *Gaceta Medica de Mexico* 151:5 (2015), pp. 640-647. [https://www.anmm.org.mx/GMM/2015/n5\\_english/2331AX155\\_151\\_2015\\_UK5\\_640-647.pdf](https://www.anmm.org.mx/GMM/2015/n5_english/2331AX155_151_2015_UK5_640-647.pdf).

23. Neeraj Sood et al., “Behind-the-Counter Statins: A Silver Bullet for Reducing Costs and Increasing Access?,” *Health Services Research* 47:1.1 (February 2012), pp. 174-187. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3447239>.

24. “Global Oral Contraception Availability,” OCs OTC Working Group, <http://ocsofc.org/world-map>.

16. Peter Temin, “Realized Benefits from Switching Drugs,” *The Journal of Law and Economics* 35:2 (October 1992), pp. 351-69. <https://www.journals.uchicago.edu/toc/ije/1992/35/2>.

17. “History of Federal Regulation: 1902-Present.” <https://www.fdareview.org/issues/history-of-federal-regulation-1902-present/#p06>.

18. Reilly. <https://dash.harvard.edu/bitstream/handle/1/8965550/Reilly06.html?sequence=2>.

19. “Durham-Humphrey Amendment,” *Rx Wiki*, Oct. 28, 2012. [http://rx-wiki.org/index.php?title=Durham-Humphrey\\_Amendment](http://rx-wiki.org/index.php?title=Durham-Humphrey_Amendment).

- Asthma inhalers (most common type) and theophylline (asthma medicine) do not require a prescription in Australia, the United Kingdom, Portugal or Mexico.<sup>25</sup>
- Naloxone (opioid overdose antidote) is available OTC in Australia, Italy and Canada.<sup>26</sup>
- Nystatin (anti-fungal agent) does not require a prescription in Australia.<sup>27</sup>
- Insulin (diabetes treatment) does not require a prescription in Canada or Mexico; and two types of insulin, Humulin and Novolin, are available without a prescription in the United States.<sup>28</sup>

Health ministries have determined that these drugs are safe enough for OTC availability. In the case of the cholesterol-lowering drug simvastatin, for instance, the U.K. Committee on Safety of Medicines found the “balance of potential health benefits and any possible risks [to be] overwhelmingly positive.”<sup>29</sup>

### A THIRD WAY: PHARMACISTS

The United Kingdom, Australia and New Zealand have a third drug category—“pharmacist-only” also referred to as “behind-the-counter”—for drugs that require the intervention of a pharmacist before dispensing to a patient.<sup>30</sup> Roughly 50 percent of the OTC drugs in the United Kingdom are “pharmacist-only.”<sup>31</sup> It can be argued that this category is not truly OTC because of the requirement to visit the pharmacist’s counter and, ultimately, have the pharmacist sign-off on the purchase. However, “behind-the-counter” is an incremental improvement over the prescription-only category and it confers cost savings.

A similar approach has been taken in several instances in the United States. A “pharmacy access” or “pharmacist-prescribing” model has emerged as a state-level effort to increase access to certain drugs that could previously only be prescribed by a doctor, physician assistant or nurse practitioner. Hormonal contraception, opioid antagonists, smoking cessation products, immunizations and certain travel medications are all furnished or dispensed by pharmacists in certain states. This model has grown in popularity over the last several years because of the push to disintermediate certain drugs based on their safety and wide use.

For example, the American College of Obstetricians and Gynecologists (ACOG), which is the largest OB-GYN association in the country, has advocated for oral contraceptives to be made available OTC for years.<sup>32</sup> This is due to the relatively few dangerous contraindications for women seeking to use birth control, and its safe, widespread use throughout the last 60 years. Further, research shows women can easily self-assess whether they have contraindications for hormonal birth control use based on simple criteria.<sup>33</sup> In addition to the added costs associated with taking time off for doctor visits to get prescriptions, there is research to suggest that prescription requirements contribute significantly to the high rate of contraceptive discontinuation within the first year and removing that barrier increases continuation.<sup>34</sup> Further, increased access results in fewer unintended pregnancies and fewer taxpayer dollars dedicated to their publicly funded medical costs.<sup>35</sup>

Yet, despite the fact that oral contraceptives are obtained without a prescription in over 100 countries, they remain prescription-only in the United States.<sup>36</sup> The FDA is in the minority of the world’s pharmaceutical regulators with regard to its classification of oral contraceptives.<sup>37</sup> To date,

25. “Supermarkets to sell asthma inhalers over the counter,” *BBC News*, July 21, 2012, <https://www.bbc.com/news/health-18936197>; “Accessing Salbutamol Without Prescription,” *Asthma Australia*, last accessed Oct. 19, 2020. <https://asthma.org.au/blog/accessing-salbutamol-without-prescription>; Ben Taylor, “Why you might not need to see the Portuguese doctor,” *Portugal Property Guides*, July 12, 2017. <https://www.propertyguides.com/portugal/news/might-not-need-see-portuguese-doctor>; Meira Nocella, et al., “A Comparison of Pharmaceutical Product Performance of Albuterol Inhalers Available in the United States and Those Obtained in a Mexican Border Town,” *Journal of Pharmacy Technology* 31:6 (December 2015) pp. 289-295. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5990204>.

26. “Opioid overdose,” *World Health Organization*, Aug. 28, 2020. <https://www.who.int/news-room/fact-sheets/detail/opioid-overdose>.

27. “Consumer medicine information: Nilstat,” *NPS Medicinewise*, May 1, 2018. <https://www.nps.org.au/medicine-finder/nilstat-oral-drops>.

28. Tribble. <https://www.npr.org/sections/health-shots/2015/12/14/459047328/you-can-buy-insulin-without-a-prescription-but-should-you>.

29. Sue Hughes, “OTC simvastatin 10 mg gets go ahead in UK,” *Medscape*, May 1, 2004. <https://www.medscape.com/viewarticle/782980>.

30. Wendy K. Bodine, “A Third Category? Medicines Go Behind the Counter,” *Pharmacy Times*, Jan. 1, 2007. <https://www.pharmacytimes.com/publications/issue/2007/2007-01/2007-01-6231>.

31. *Ibid.*

32. Committee on Gynecologic Practice, “Opinion Number 788: Over-the-Counter Access to Hormonal Contraception,” *The American College of Obstetricians and Gynecologists*, October 2019. <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2019/10/over-the-counter-access-to-hormonal-contraception>.

33. Solmaz Soltorbani, “Agreement between women’s and providers’ assessment of hormonal contraceptive risk factors,” *Contraception* 73:5 (May 2006), pp. 501-506. <https://www.sciencedirect.com/science/article/pii/S0010782405004798>.

34. Joseph E. Potter et al., “Continuation of Prescribed Compared with Over-the-Counter Oral Contraceptives,” *Obstetrics and Gynecology* 117:3 (March 2011), pp. 551-557. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3606883>.

35. Adam Sonfield and Kathryn Kost, “Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010,” *Guttmacher Institute*, February 2015. <https://www.guttmacher.org/report/public-costs-unintended-pregnancies-and-role-public-insurance-programs-paying-pregnancy>.

36. Kate Grindlay et al., “Prescription requirements and over-the-counter access to oral contraceptives: a global review,” *Contraception* 88:1 (July 1, 2013), pp. 91-96. [https://www.contraceptionjournal.org/article/S0010-7824\(12\)01029-3/abstract?code=contra-site](https://www.contraceptionjournal.org/article/S0010-7824(12)01029-3/abstract?code=contra-site); Jeffrey Singer, “Free Birth Control from the Third-Party Trap,” *Morning Consult*, Sept. 1, 2017. <https://morningconsult.com/opinions/free-birth-control-third-party-trap>.

37. Jeffrey Singer, “End the ban on over-the-counter oral contraceptives,” *STAT News*, Dec. 19, 2017. <https://www.statnews.com/2017/12/19/oral-contraceptives-ban-otc>.



16 states and Washington, D.C. have found a way around the FDA classification by authorizing pharmacists to prescribe oral contraceptives, effectively re-classifying them as behind-the-counter in what's called the "pharmacy access" model.<sup>38</sup> This model, championed by both Republicans and Democrats, has been passed in politically diverse states like Utah, Tennessee, California and Oregon.<sup>39</sup> In fact, the majority of western states—except for Arizona, Nevada, and Wyoming—now permit pharmacists to prescribe oral contraceptives.

Beyond the issue of who can prescribe birth control, women often cannot receive more than a 90-day supply of oral contraceptives at one time. Yet some states have begun to allow women to obtain a 12-month supply, which is associated with better adherence to a birth control regimen.<sup>40</sup> Prescription refill access is crucial; for example, in response to the COVID-19 public health emergency, Arizona Gov. Doug Ducey permitted pharmacists to refill prescriptions for up to an additional 180 days, including prescription oral contraceptives.<sup>41</sup> Arizona-based patients can normally only receive a 90-day supply of birth control, so this executive order temporarily granted pharmacists the prerogative to prescribe up to six months of oral contraceptives to women.

It would not be a giant leap for states to permanently extend prescription durations for birth control. In states where pharmacists can initiate birth control prescriptions, research shows that patients seeing a pharmacist for their prescription were more likely to receive over six months' worth of birth control compared with those who went to clinics for their prescription.<sup>42</sup>

## PHARMACY ACCESS TO CONTRACEPTION IN THE UNITED STATES

States have implemented the pharmacy access model with some variance in both approach and success. California was the first state to pass legislation allowing pharmacists to prescribe certain hormonal contraceptives in 2014, but Oregon was the first to implement the practice in 2016.<sup>43</sup> The Oregon model—which initially allowed for pharmacist prescribing of self-administered oral hormonal contraception and hormonal contraceptive patches—expanded to include contraceptive injections and the vaginal ring in 2017.<sup>44</sup> Insurers are required to cover the patient-pharmacist consultation.<sup>45</sup> Contraception-specific training is required for pharmacists wishing to prescribe, and the training must be approved by the Oregon Board of Pharmacy.<sup>46</sup>

The results of the Oregon model have been positive. Better access to contraception through expanding the pharmacist scope of practice increases women's abilities to control and achieve their family planning desires; reduces unintended pregnancies and their consequences; and saves taxpayer dollars spent on the health care costs associated with those pregnancies. For example, in 2010, 46 percent of pregnancies in Oregon were unintended.<sup>47</sup> Almost 70 percent of those pregnancies were publicly funded, costing taxpayers \$170 million in health care costs accrued for prenatal and postpartum services.<sup>48</sup> Over \$47 million of these costs were directly shouldered by the state government.<sup>49</sup> However, in the first two years of allowing pharmacists to prescribe, pharmacists wrote 10 percent of all new birth control prescriptions among Oregon Medicaid enrollees and prevented an estimated 50 unintended pregnancies for that same population.<sup>50</sup> The resultant savings to the state is an estimated \$1.6 million.<sup>51</sup> These cost savings are likely to grow as the pharmacy access model becomes a better-known, accessible option for patients.

38. Courtney M. Joslin, "Lessons for Legislators: A Guide to Allowing Pharmacist-Prescribed Birth Control," *R Street Policy Papers* No. 207, September 2020, <https://www.rstreet.org/2020/09/30/lessons-for-legislators-a-guide-to-allowing-pharmacist-prescribed-birth-control>.

39. "Pharmacist Prescribing of Contraception," Power to Decide, last accessed Oct. 1, 2020, <https://powertodecide.org/what-we-do/access/state-policy/rh-access-policies/pharmacist-prescribing>.

40. "Twelve-Month Supply of OCs Cost-Effectively Prevented More Unintended Pregnancies," U.S. Pharmacist, July 25, 2019, <https://www.uspharmacist.com/article/twelvemonth-supply-of-ocs-costeffectively-prevented-more-unintended-pregnancies>; Colleen P. Judge-Golden et al., "Financial Implications of 12-Month Dispensing of Oral Contraceptive Pills in the Veterans Affairs Health Care System," *JAMA Internal Medicine* 179:9 (July 8, 2019), pp. 1201-1208, <https://pubmed.ncbi.nlm.nih.gov/31282923>.

41. Office of the Gov. Doug Ducey, "New Order Allows Certain Prescription Refills Without Having to See a Doctor," Press Release, April 2, 2020, <https://azgovernor.gov/governor/news/2020/04/new-order-allows-certain-prescription-refills-without-having-see-doctor>.

42. Maria I. Rodriguez et al., "Association of Pharmacist Prescription With Dispensed Duration of Hormonal Contraception," *JAMA Network Open* 3:5 (2020), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2766072>.

43. Jeffrey A. Singer, "Women Should Not Have to Visit a Doctor for Birth Control," *TIME*, Jan. 14, 2016, <http://time.com/4180612/birth-control-prescriptions>.

44. "Oregon Expands Pharmacists' Authority to Dispense Contraceptives," Association of State and Territorial Health Officials, July 27, 2017, <https://astho.org/StatePublicHealth/Oregon-Expands-Pharmacists-Authority-to-Dispense-Contraceptives/7-27-17/#:~:text=Oregon%20Expands%20Pharmacists'%20Authority%20to%20Dispense%20Contraceptives&text=In%202015%2C%20Oregon%20enacted%20HB,contraceptives%20and%20hormonal%20contraceptive%20patches>.

45. H. B. 2879, 78th Oregon Legislative Assembly, 2015, <https://olis.leg.state.or.us/liz/2015R1/Downloads/MeasureDocument/HB2879/Enrolled>.

46. *Ibid.*

47. "State Facts About Unintended Pregnancy: Oregon," Guttmacher Institute, September 2016, [https://www.guttmacher.org/sites/default/files/factsheet/or\\_17.pdf](https://www.guttmacher.org/sites/default/files/factsheet/or_17.pdf).

48. *Ibid.*

49. *Ibid.*

50. Tracy Brawley, "Pharmacist-prescribed birth control reaches new users, saves Oregon \$1.6M," Oregon Health and Sciences University, May 9, 2019, <https://news.ohsu.edu/2019/05/09/pharmacists-prescribed-birth-control-reaches-new-contraceptive-users-saves-oregon-1-6-million-in-public-costs>.

51. *Ibid.*

## CONSIDERATIONS FOR IMPLEMENTATION

Oregon's success makes them the model to follow for other states seeking to enact a pharmacy access system. But states with the pharmacy access model have, on some fronts, approached this model differently, which has affected implementation and reach. First, some states do not allow pharmacists to prescribe the full range of appropriate hormonal contraceptives. For example, Colorado does not include the vaginal ring as an approved pharmacist-prescribed method even though every other state that allows pharmacist-prescribed contraception does.<sup>52</sup> Additionally, the contraceptive shot that Oregon began to include in 2017 is only approved in three other states.<sup>53</sup> Pharmacists provide injections already—such as flu vaccines—so there is no reason to limit this range of birth control prescriptions from pharmacists.

Further, some states have enacted age restrictions—most commonly 18 and above—for pharmacist-issued birth control prescriptions. These age restrictions are medically unnecessary; it is well-documented that younger patients have fewer contraindications than older ones, especially those under 35—meaning that younger patients are the safest demographic of birth control users.<sup>54</sup>

Finally, states with the pharmacy access model—and even some without—have expanded pharmacist duties in other areas. While most states in recent years have focused largely on allowing pharmacy access to contraception, many states now allow pharmacists to prescribe or supply a variety of travel medications, smoking cessation products, opioid antagonists and immunizations.<sup>55</sup> These changes were made to allow easier access to routine, but important, medications. Now, pharmacists in every state have the ability to administer some range of immunizations, which has directly increased the rate of vaccines given.<sup>56</sup> Normally, some states that allow pharmacists to administer vaccines restrict this ability to certain vaccination recommendations from the Centers for Disease Control and Prevention; however, the U.S. Department of Health and Human Services issued an amendment in August 2020 allowing pharmacists to administer vaccines to patients three years old and older during the COVID-19

pandemic.<sup>57</sup> This amendment temporarily overrides restrictions that some states have on pharmacist-administered vaccines.<sup>58</sup> Similarly, increasing pharmacist scope of practice to include opioid antagonists has contributed to a decline in opioid overdose deaths.<sup>59</sup>

## PHARMACY ACCESS TO NALOXONE

Another use of the pharmacy access model relates to the opioid overdose crisis. Naloxone, the opioid overdose-reversal drug created in 1971, has been available OTC in Australia since 2016 and in Italy since 1996.<sup>60</sup> On April 5, 2018, the U.S. Surgeon General issued an advisory drawing attention to the effectiveness of naloxone and urging the widespread availability and distribution to the public of the overdose antidote in response to the national opioid overdose crisis.<sup>61</sup> However, in the United States it is still classified as a prescription-only drug.<sup>62</sup> All 50 states plus the District of Columbia have found ways around the classification in an attempt to make it more widely available. In most cases, the states' chief medical officer issues a "standing order" to pharmacists to dispense the drug to patients approaching the pharmacy counter.<sup>63</sup> Other states have legally empowered the pharmacist to be the prescribing licensed health care practitioner.<sup>64</sup> This effectively makes naloxone a behind-the-counter drug in the United States. The results have been promising; pharmacist distribution of naloxone has led to fewer overdose deaths in the nation.<sup>65</sup>

52. Sally Rafie and Sharon Landau, "Opening New Doors to Birth Control: State Efforts to Expand Access to Contraception in Community Pharmacies," *Birth Control Pharmacist*, Dec. 21, 2019. <https://birthcontrolpharmacist.com/2019/12/21/report>.

53. *Ibid.*

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However, experience has shown that many opioid users or their friends or family members do not avail themselves of the drug because of the inconvenience of the behind-the-counter status combined with their reluctance to reveal their now-stigmatized opioid use.<sup>66</sup> Further, there are numerous reports of pharmacists refusing to participate in naloxone distribution—some because they believe they are enabling a dangerous drug habit—which has obstructed its use and wider distribution.<sup>67</sup> This problem could be ameliorated by reclassifying naloxone as truly OTC.<sup>68</sup>

## STATES CAN EASE COSTS AND IMPROVE PATIENT AUTONOMY

While federal action is required to reclassify drugs from prescription-only to OTC, states have the authority to determine the scope of practice of the health care practitioners they license. State lawmakers can expand the scope of licensed pharmacists to enable them to prescribe a wide range of medications to patients who would not otherwise need to consult a physician. Pharmacists receive advanced training in cardiovascular disease risk management, patient-centered diabetes care and immunizations. Their scope of practice should be expanded to enable them to practice to the full extent of their training. These expansions still uphold safety standards that are currently practiced in the medical community. For example, pharmacists can still require that a patient receive a prescription from a physician, nurse practitioner or physician's assistant if they make that professional determination when interacting with patients. Furthermore, patients will still be able to seek the advice of a physician, nurse practitioner or physician's assistant should they desire additional expertise before seeking treatment. And finally, pharmacists are not required to offer these prescription services. Instead, the pharmacy access model voluntarily expands pharmacists' scope of practice and expands patients' range of options and autonomy.

Pharmacists are already gaining ground in many states when it comes to their scope of practice.<sup>69</sup> Pharmacists provide added convenience and access to care while reducing costs for patients. Lawmakers should expand upon this proven approach to include:

- Hormonal contraception like birth control pills, patches, vaginal rings and injections.
- OTC nicotine replacement products as well as FDA-approved prescription products indicated to aid in smoking cessation treatment for eligible patients.
- Oral fluoride varnish to eligible patients.
- Tuberculin Skin Test (TST) administration and results interpretation for the purposes of referral and treatment following a positive test.
- FDA-approved prescription medications to eligible patients testing positive for influenza or strep throat.
- FDA-approved non-sedating and low-sedating anti-histamines, corticosteroids, decongestants, saline, sodium cromolyn and leukotriene receptor antagonists.
- Permanent implementation of emergency executive orders, like Arizona Gov. Ducey's, to allow pharmacists to extend routine, non-controlled, chronic medications for up to an additional 180 days.

## CONCLUSION

The pharmacy access model capitalizes on the opportunity to increase patient access to medical providers and sensibly expands pharmacist scope of practice to include services they are well-equipped to perform. States that have expanded pharmacist-prescribing to include things like birth control, smoking cessation drugs and more immunizations provide a model for other states to follow. While not truly an OTC model, allowing pharmacists to prescribe is a state-based effort to get around the federal barriers put in place by the FDA.

States like Oregon and Utah that have expanded their pharmacy access programs have set an example that other states can look to in enacting patient-centric policies. While federal efforts lag behind, state lawmakers can ensure that citizens have increased autonomy, freedom to choose and healthier lives overall.

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