

Resistance and Resilience: Antibiotic Tracking to Thwart Antimicrobial Resistance

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RESISTANCE AND RESILIENCE: ANTIBIOTIC TRACKING TO THWART ANTIMICROBIAL RESISTANCE

JORDAN M. FISHER*

“Bacteria will inevitably find ways of resisting the antibiotics we develop.”¹

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1. CTRS. FOR DISEASE CONTROL & PREVENTION, ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES, 2013, at 12 (2013) [hereinafter CDC, ANTIBIOTIC RESISTANCE].

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I. INTRODUCTION

Antibiotic resistant “superbugs” are a concerning public health threat in the United States and worldwide. Antibiotic resistance refers to infections that are resistant to current antibiotics.² The rise of these superbugs requires innovative public health responses to these emerging microbial threats. This article seeks to advocate for an innovative, twenty-first century solution using traditional health department responses: tracking, monitoring, and surveillance. These activities—which can be conducted through the existing infrastructure of Prescription Drug Monitoring Programs (PDMP)—would allow states, counties, and localities to track and monitor antimicrobial resistance.

II. ANTIBIOTICS AND RESISTANCE

Antibiotic resistance presents a complex multifaceted problem which requires groundbreaking solutions. To understand the underlying issues, this article begins by providing background on antibiotics and the rise of antibiotic resistant bacteria, followed by an overview of the existing federal legal landscape in this area.³ Next, this article looks at the historical goals and functions of State health departments regarding surveillance of emerging diseases.⁴ Then, this article seeks to explain the existing infrastructure of PDMPs and innovative uses of these programs.⁵

2. *Antibiotic Prescribing & Use in Doctor’s Offices: Antibiotic Resistance Q&As*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/antibiotic-use/community/about/antibiotic-resistance-faqs.html> (Aug. 23, 2021). “Antibiotic resistance happens when the germs no longer respond to the antibiotics designed to kill them. That means the germs are not killed and continue to grow . . . [A]ntibiotic-resistant germs are difficult, and sometimes impossible, to treat.” *Id.*

3. See *infra* Parts II.A–C.

4. See *infra* Part II.D.

5. See *infra* Parts II.E–F.

A. Antibiotics: Past to Present

The modern era of antibiotics began in 1928 with Alexander Fleming's discovery of penicillin.⁶ Even after this momentous discovery, by the 1950s, penicillin resistant infections began to emerge.⁷ We now see antibiotic resistance in almost all known antibiotics.⁸ In response to this problem, various new antibiotics were introduced from the 1960s through the early 1980s. Now, however, fewer new antibiotics are being introduced.⁹ Since the 1970s, no new antibiotic classes have been discovered.¹⁰ Major pharmaceutical companies have reduced their antibiotic development because antibiotics are curative and often not used for chronic conditions and are therefore less profitable than other pharmaceutical innovations.¹¹ Further contributing to lack of profitability is that the emerging best practice is to hold a new antibiotic in reserve for only severely resistant cases.¹² The World Health Organization (WHO) has classified antibiotics in three groups: access, watch, and reserve.¹³ This classification serves as guidance on which antibiotics should be used day-to-day (access), which ones should be used cautiously (watch), and which ones should be used only as the last resort (reserve).¹⁴ Even with the emerging problem of resistance, antibiotics play a pivotal role in modern medicine and remain important in treating infections which were once considered deadly.¹⁵

6. C. Lee Ventola, *The Antibiotic Resistance Crisis: Part 1: Cases and Threats*, 40 PHARMACY & THERAPEUTICS 277, 277 (2015).

7. *Id.*

8. *Id.*

9. *Id.* at 278.

10. Rustam I. Aminov, *A Brief History of the Antibiotic Era: Lessons Learned and Challenges for the Future*, FRONTIERS MICROBIOLOGY, Dec. 8, 2010, at 1, 3. Typically, antibiotics are classified by their chemical structure. *Antibiotic Resistance Patient Safety Atlas: Outpatient Antibiotic Prescription Data*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://arpsp.cdc.gov/resources/OAU-Antibiotic-Class-Definitions.pdf> (last visited Feb. 4, 2022). Some antibiotics kill bacteria, while others keep the bacteria from multiplying. *Id.* For example, “[c]ephalosporins kill bacteria by preventing formation of the bacterial cell wall” while “[f]luoroquinolones kill bacteria by keeping bacteria from making DNA.” *Id.*

11. Ventola, *supra* note 6, at 279.

12. *Id.* at 279–80.

13. WORLD HEALTH ORG., EXECUTIVE SUMMARY: THE SELECTION AND USE OF ESSENTIAL MEDICINES 1 (2017).

14. *Id.* at 2–4; see also Ariana Eunjung Cha, *WHO Creates Controversial ‘Reserve’ List of Antibiotics for Superbug Threats*, WASH. POST (June 6, 2017), <https://www.washingtonpost.com/news/to-your-health/wp/2017/06/06/who-creates-controversial-reserve-list-of-antibiotics-in-new-response-to-superbug-threats/> (explaining the three antibiotic categories and providing a brief description of each).

15. See Ventola, *supra* note 6, at 278 (“Antibiotics have also helped to extend expected life spans by changing the outcome of bacterial infections. In 1920, people in the U.S. were expected to live to only be 56.4 years old; now, however, the average U.S. life span is nearly 80 years.”).

B. Antibiotic Resistant “Superbugs”

Antibiotic resistant bacteria are considered by the WHO to be “one of the biggest threats to global health, food security, and development.”¹⁶ The Centers for Disease Control and Prevention (CDC) views antibiotic resistance as one of the biggest modern public health challenges.¹⁷ Each year in the United States, over 2.8 million people contract an antibiotic-resistant infection, and “[m]ore than 35,000 people die.”¹⁸ Alexander Fleming, upon winning the Nobel Prize for his discovery of penicillin, cautioned of the dangers of misuse of his antibiotic which could lead to organisms that resist penicillin.¹⁹ Currently, “methicillin-resistant *Staphylococcus Aureus* (MRSA), kills more Americans every year than emphysema, HIV/AIDS, Parkinson’s disease, and homicide combined.”²⁰ While extremely difficult to calculate the total economic cost of these infections, estimates indicate the cost could be as high as \$20 billion a year in direct healthcare related costs and additional costs to society for loss of productivity as high as \$35 billion a year.²¹ Antibiotic resistance has caused devastation for many individuals and families including: nine year-old Kenna who faced necrotizing pneumonia, a heart valve infection, an abscess in her thigh, and ten days on a ventilator from a MRSA infection; fifty seven year-old George who faced six surgeries related to an infection resistant to virtually every antibiotic; and eleven year-old Addie who spent five months in the hospital, three months on a machine which circulated her blood and added oxygen to it, and ultimately required a double lung transplant due to a resistant infection.²²

16. *Antibiotic Resistance*, WORLD HEALTH ORG. (July 31, 2020), <https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance>.

17. *Antibiotic/Antimicrobial Resistance*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugresistance/about.html> (Dec. 13, 2021).

18. *Id.*

19. Cory Fox, *Resisting Antibiotic Resistance: Legal Strategies to Maintain Man’s Dominion Over Microbes*, 12 HOUS. J. HEALTH L. & POL’Y 35, 37–38 (2011).

20. Erin LaMontagne, Comment, *Off-Label Promotion, the First Amendment, and Practically Addressing Antibiotic Resistance*, 51 CAL. W. L. REV. 293, 295 (2015) (citing Infectious Disease Soc’y of Am., *Combating Antimicrobial Resistance: Policy Recommendations to Save Lives*, 52 (Supp. 5) CLIN. INFECTIOUS DISEASES S397–S428, S397 (2011)).

21. CDC, ANTIBIOTIC RESISTANCE, *supra* note 1, at 11; *see also* Ventola, *supra* note 6, at 283 (explaining that “the medical cost per patient with an antibiotic resistant infection range[s] from \$18,588 to \$29,069.”).

22. *Patient Stories: The Faces of Antimicrobial Resistance*, INFECTIOUS DISEASE SOC’Y OF AM., <https://www.idsociety.org/public-health/patient-stories/patient-stories/> (last visited Feb. 13, 2022); *Patient Stories: Kenna Van Kirk*, INFECTIOUS DISEASE SOC’Y OF AM., <https://www.idsociety.org/public-health/patient-stories/kenna-van-kirk/> (last visited Feb. 13, 2022); *Patient Stories: George Semakula*, INFECTIOUS DISEASE SOC’Y OF AM., <https://www.idsociety.org/public-health/patient-stories/george-semakula/> (last visited Feb. 13, 2022); *Patient Stories: Addie Rerecich*, INFECTIOUS DISEASE SOC’Y OF AM., <https://www.idsociety.org/public-health/patient-stories/addie-rerecich/> (last visited Feb. 13, 2022). For further discussion, see INFECTIOUS DISEASE SOC’Y OF AM., *FACES OF ANTIMICROBIAL RESISTANCE*, <https://www.idsociety.org/globalassets/bb-complex-pages/pdf/foar-report-1-up-final.pdf> (describing other individuals whose stories demonstrate the urgent need to combat antimicrobial resistance).

While antibiotics have saved countless lives since their discovery in the 1940s, any use of antibiotics can also result in antibiotic resistance.²³ While antibiotic resistance cannot be attributed to a single cause, there are significant human-caused factors that contribute to their resistance, including: (1) overuse through over-prescription, (2) misuse through failure to complete the course of treatment, (3) failure to contain antibiotic-resistant infections in healthcare settings, (4) factory farming and sub-therapeutic use in meat products, and (5) barriers to pharmaceutical innovation.²⁴ As such, “[w]hile superbugs are a frightening reminder of the adaptability and ingenuity of microorganisms, they are also the direct result of mankind’s chronic misuse and persistent overuse of antibiotics.”²⁵ Since antibiotic resistance is a complex, multifaceted issue, some of these factors are outside the scope of this article, which focuses on antibiotic misuse and overuse.²⁶

Antibiotic misuses involves two distinct sub-sets of activities: (1) when an antibiotic is properly prescribed by a clinician and then is not taken as prescribed or completed by the patient, and (2) when an antibiotic is improperly prescribed by a clinician.²⁷ Antibiotic overuse occurs when stronger, broad-spectrum antibiotics are used to treat an infection that could be treated with a much weaker, narrow-spectrum antibiotic.²⁸ A strong correlation exists between the level of antibiotic resistant infections and the level of antibiotic use.²⁹ The magnitude of the problem becomes apparent through the CDC’s estimation that thirty percent of all antibiotics prescribed are for conditions that do not require their use.³⁰ The CDC has also found that urgent care facilities are the most frequent prescribers of unnecessary antibiotics.³¹ In some states, there are more antibiotics prescribed per year than there are people.³² To further understand the complexity of

23. CDC, ANTIBIOTIC RESISTANCE, *supra* note 1, at 41.

24. Donna Hanrahan, *Combating Resistance: Federal Efforts to Reduce Overuse, Curb Misuse, and Incentive the Development of Antibiotic Drugs*, 26 ANNALS HEALTH L. 67, 70–71 (2017).

25. Fox, *supra* note 19, at 36.

26. *See id.* at 68 (explaining that the article addresses antibiotic resistance and makes recommendations to reduce overuse, misuse, and encourage novel antibiotic drug development).

27. LaMontagne, *supra* note 20, at 303–04.

28. *Id.* at 304. Antibiotics include a range of spectrums: broad spectrum, intermediate spectrum, or narrow spectrum. *Antibiotic Resistance Learning Site: Spectrum of Activity*, UNIV. OF MINN. <https://amrls.umn.edu/pharmacology> (last visited Jan. 28, 2022). As the name suggests, a broad spectrum antibiotic can work against a variety of bacterium. *Id.* In contrast, narrow spectrum antibiotics are typically only effective against specific microorganisms. *Id.*

29. Aminov, *supra* note 10, at 4.

30. CTRS. FOR DISEASE CONTROL & PREVENTION, 2018 UPDATE ANTIBIOTIC USE IN THE UNITED STATES PROGRESS AND OPPORTUNITIES 3 (2019), <https://www.cdc.gov/antibiotic-use/stewardship-report/pdf/stewardship-report-2018-508.pdf> [hereinafter CDC, 2018 UPDATE].

31. *Id.* at 5. For example, providers in urgent care settings prescribe antibiotics unnecessarily in forty six percent of the respiratory infections they treat. *Id.* Additionally, urgent cares also have the largest percentage for visits resulting in an antibiotic prescription. *Id.*

32. Ventola, *supra* note 6, at 278.

antibiotics and their governance it is important to acknowledge the existing legal landscape within the United States.

C. Existing Legal Landscape

Within the United States, powers are separated between the state and federal governments.³³ While the United States has a system of federalism, however, “[t]here is no bright line separating federal and state authorities. In reality, governments’ respective powers have historically overlapped, especially in areas like public health.”³⁴ Antibiotic resistance can also implicate international concerns which further blurs the lines between state and federal responsibility.³⁵ Traditionally, however, antibiotic resistance has been largely monitored by federal agencies due to their greater institutional competencies.

1. Existing Federal Law Combatting Antibiotic Resistance

While various congressional proposals have been introduced to address antibiotic resistance, these proposals largely have failed.³⁶ Nevertheless, on September 18, 2014, President Obama issued Executive Order 13676 which sought to address antibiotic resistance.³⁷ Among other things, the Executive Order established antibiotic-resistant bacteria as a national security priority and created a Task Force for Combating Antibiotic Resistant Bacteria, which endeavored to improve antibiotic stewardship, strengthen national surveillance, and promote new antibiotic development and international cooperation.³⁸ Alongside the Executive Order, the United States National Strategy for Combating Antibiotic-Resistant Bacteria was released.³⁹ While there is limited codified law, various agencies have begun to promulgate regulations and engage in activities designed to combat antibiotic resistance. For example, the Federal Health and Human Services’ Office of the Assistant Secretary for Preparedness and Response focuses on the national security threat caused by antibiotic-

33. JAMES G. HODGE, JR., *PUBLIC HEALTH LAW IN A NUTSHELL*, 36–37 (4th ed. 2022).

34. *Id.*

35. See *Antibiotic Resistance*, *supra* note 16 (outlining the severe impact antibiotic resistance has on global health, food security, and the healthcare system).

36. Andrew Geltman, Comment, *Defusing the Bug Bomb: Legal Strategies to Combat Antibiotic Resistant Infections*, 18 J. HEALTH CARE L. & POL’Y 115, 117 n.18 (2015).

37. Off. of the Press Sec., *Executive Order—Combating Antibiotic-Resistant Bacteria*, WHITE HOUSE: PRESIDENT BARACK OBAMA (Sept. 18, 2014), <https://obamawhitehouse.archives.gov/the-press-office/2014/09/18/executive-order-combating-antibiotic-resistant-bacteria>.

38. *Id.*

39. *Antibiotic/Antimicrobial Resistance: National Strategy*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 2014), <https://www.cdc.gov/drugresistance/us-activities/national-strategy.html>. The national strategy outlines five goals which include: (1) slowing and preventing the spread of resistant bacteria and infections, (2) strengthening surveillance efforts, (3) advancing development of diagnostic testing for identification of resistant bacteria, (4) accelerating research and development for new antibiotics, other therapeutics, and vaccines, and (5) improving international collaboration. *Id.*

resistance.⁴⁰ The remainder of Part II.C.1. will highlight the work of the two Federal agencies who are most closely involved in this issue: The CDC and The Food and Drug Administration (FDA).

a. Efforts by the CDC

The CDC is tasked with being “the lead agency for prevention, health data, epidemic investigation, and public health measures aimed at disease control and prevention.”⁴¹ The CDC seeks to combat antibiotic resistance with various programs and initiatives.⁴² In fiscal year 2016, Congress appropriated \$160 million to the CDC to fight antibiotic resistance with an additional \$163 million and \$168 million provided in fiscal years 2017 and 2018, respectively.⁴³ Some of the programs administered by the CDC include: the AR Solutions Initiative; an antibiotic stewardship program; the National Healthcare Safety Network (NHSN); and other tracking and surveillance programs.⁴⁴

i. AR Solutions Initiative

The AR Solutions Initiative is a CDC program that seeks to empower the country to adequately respond to the emerging threat of antibiotic resistance.⁴⁵ In addition, the “[i]nitiative invests in national infrastructure to detect, respond, contain, and prevent resistant infections across healthcare settings, food, and communities.”⁴⁶ The AR Solutions Initiative has also established the AR Lab Network which is a network of CDC labs that have expanded the testing capacity of all state and local health departments.⁴⁷ This expanded testing capacity fills data gaps and allows better-informed responses to best determine treatment for emerging resistant bacteria.⁴⁸ Additional functions of the AR Lab Network include rapid detection of antibiotic resistant infections to inform the local

40. *Fight Against Superbugs Crucial to America’s Biodefense*, PEW CHARITABLE TRS. (Feb. 1, 2019), <https://www.pewtrusts.org/en/research-and-analysis/articles/2019/02/01/fight-against-superbugs-crucial-to-americas-biodefense>.

41. SARAH E. WILENSKY & JOEL B. TEITELBAUM, *ESSENTIALS OF HEALTH POLICY AND LAW* 88 (4th ed. 2019).

42. *See generally Antibiotic/Antimicrobial Resistance*, *supra* note 17 (identifying eight key resources and programs within the CDC that combat antibiotic resistance).

43. *Antibiotic/Antimicrobial Resistance: What CDC is Doing: AR Solutions Initiative*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugresistance/solutions-initiative/index.html> (March 2, 2022) [hereinafter *Antibiotic/Antimicrobial Resistance: What CDC is Doing*].

44. *Id.*; *see also* CDC, *ANTIBIOTIC RESISTANCE*, *supra* note 1, at 39–40 (outlining the serious health threat antimicrobial resistance has on public health).

45. CDC, *ANTIBIOTIC RESISTANCE*, *supra* note 1, at 39–40.

46. *Antibiotic/Antimicrobial Resistance: What CDC is Doing*, *supra* note 43.

47. *Fighting Antibiotic Resistance*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/ncezid/pdf/two-pagers/NCEZID-antibiotic-resistance-2pgr-H.pdf> (last visited Apr. 17, 2022).

48. *Id.*

response teams, DNA sequencing, and the use of data to drive infection prevention.⁴⁹

ii. CDC Antibiotic Stewardship

The CDC also administers a guidance program for medical providers on how they should prescribe and use antibiotics.⁵⁰ Changing the way antibiotics are used can drastically slow the spread of antibiotic resistance.⁵¹ Antibiotic stewardship refers to the promotion of the correct use of antibiotics, a reduction in resistance, and a decrease in the spread of resistant infections.⁵² The CDC identifies the four core elements of antibiotic as: (1) commitment, (2) action for policy and practice, (3) tracking/reporting, and (4) education.⁵³ Through this initiative, the CDC seeks to maximize the benefit of antibiotics while minimizing harm to individuals and the public through its various educational, tracking, and antibiotic stewardship programs that seek to educate providers and individuals regarding the correct use of antibiotics.⁵⁴

iii. CDC's National Healthcare Safety Network

The National Healthcare Safety Network is an important CDC tracking tool that collects and tracks data on resistant infections that occur in health care facilities.⁵⁵ NHSN allows for facility-specific tracking that can assist individual facilities in combatting these infections and choosing the right antibiotics in the future.⁵⁶ Unfortunately, this tracking only focuses on healthcare-associated infections and does not provide data for community-associated infections.⁵⁷ Nevertheless, “NHSN provides facilities, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and

49. *Lab Capacity in Action to Fight Antibiotic Resistance*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugresistance/solutions-initiative/ar-lab-network.html> (last visited Nov. 23, 2021).

50. See *Core Elements of Antibiotic Stewardship*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/antibiotic-use/core-elements/index.html#:~:text=Antibiotic%20stewardship%20is%20the%20effort,use%2C%20and%20combat%20antibiotic%20resistance> (Apr. 7, 2021) (providing guidance relating to core elements and implementation of antibiotic stewardship programs in various healthcare settings including: hospitals, outpatient centers, nursing homes, small and critical access hospitals, and resource-limited settings).

51. CDC, ANTIBIOTIC RESISTANCE, *supra* note 1, at 31.

52. CTRS. FOR MEDICARE & MEDICAID SERVS., A FIELD GUIDE TO ANTIBIOTIC STEWARDSHIP IN OUTPATIENT SETTINGS 3 (2018).

53. CTRS. FOR DISEASE CONTROL & PREVENTION, THE CORE ELEMENTS OF OUTPATIENT ANTIBIOTIC STEWARDSHIP 15, https://www.cdc.gov/antibiotic-use/community/pdfs/16_268900-A_CoreElementsOutpatient_508.pdf [hereinafter CDC, THE CORE ELEMENTS].

54. *Id.* at 6.

55. CDC, ANTIBIOTIC RESISTANCE, *supra* note 1, at 40.

56. *Id.*

57. *National Healthcare Safety Network (NHSN): About NHSN*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/nhsn/about-nhsn/index.html> (Jan. 25, 2021).

ultimately eliminate healthcare-associated infections.”⁵⁸ For fiscal year 2020, Congress has provided \$21 million to the CDC for NHSN to increase hospital reporting of antibiotic use and resistance.⁵⁹ The Centers for Medicare and Medicaid Services (CMS) has also made certain incentive-based payments contingent on reporting these measures to the CDC.⁶⁰ Overall, the CDC has found that tracking and reporting clinician antibiotic prescribing “can guide changes in practice and can be used to assess progress in antibiotic prescribing.”⁶¹

b. Efforts by the FDA

The FDA is another pivotal player in combatting antibiotic resistance.⁶² The FDA is committed to addressing antibiotic resistance through the following strategies: (1) facilitating product development for new antibiotics, diagnostic tests, and vaccines; (2) promoting appropriate use of antibiotics, education, and other resources; (3) supporting the development of surveillance tools; and (4) advancing regulatory science.⁶³ To encourage new development, the FDA uses a variety of tools including fast track designation, priority review, and breakthrough therapy designation.⁶⁴ In addition to addressing antibiotic resistance on humans, the FDA works to promote the appropriate use of antibiotics in veterinary settings to complement the work of other federal agencies in healthcare settings.⁶⁵ As such, in 2003, the FDA established industry-wide guidance for assessing antibiotic resistance in the FDA approval process for animal drugs.⁶⁶

58. *Id.*

59. David Hyun & Ariana Olshan, *Congress Seeks to Boost Hospital Reporting of Antibiotic Use*, PEW CHARITABLE TRS. (Dec. 20, 2019), <https://www.pewtrusts.org/en/research-and-analysis/articles/2019/12/20/congress-seeks-to-boost-hospital-reporting-of-antibiotic-use>.

60. CTRS. FOR DISEASE CONTROL & PREVENTION & CTRS. FOR MEDICARE & MEDICAID SERVS., *Adherence to the Centers for Disease Control and Prevention’s (CDC’s) Infection Definitions and Criteria is Needed to Assure Accuracy, Completeness, and Comparability of Infection Control*, <https://www.cdc.gov/nhsn/pdfs/cms/NHSN-Reporting-signed.pdf>.

61. CDC, THE CORE ELEMENTS, *supra* note 53, at 20.

62. See *Antimicrobial Resistance Information from FDA*, FOOD & DRUG ADMIN., <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/antimicrobial-resistance-information-fda> (Mar. 2022) (highlighting the FDA’s role and strategic approach to antimicrobial resistance).

63. *Id.*

64. *Id.*

65. *Id.*; see also FOOD & DRUG ADMIN., SUPPORTING ANTIMICROBIAL STEWARDSHIP IN VETERINARY SETTINGS: GOALS FOR FISCAL YEARS 2019-2023 (2018) (discussing actions being taken by the FDA’s Center for Veterinary Medicine and other stakeholders to support antimicrobial stewardship in veterinary settings).

66. *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbial Effects on Bacteria of Human Health Concern*, FOOD & DRUG ADMIN. (Oct. 2003), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-152-evaluating-safety-antimicrobial-new-animal-drugs-regard-their-microbiological-effects>; *Timeline of FDA Action on Antimicrobial*

D. State and Local Health Departments: Objectives and Activities

Public health has traditionally been a state law objective since it falls under the scope of states' police power.⁶⁷ Generally, the role of State and local Departments of Health includes screening for diseases, treatment, training programs, state laboratory services, epidemiology, and surveillance.⁶⁸ There are ten essential public health services established by The Core Public Health Functions Steering Committee in 1994.⁶⁹ Of these ten services, the most important for the purposes of this article include: monitoring to address community health problems, diagnosing and investigating health concerns in the community, and providing information and education to the public about public health concerns.⁷⁰ These essential public health services denote some of the traditional areas in which state and local health departments have engaged and deployed their resources.

1. Surveillance, Monitoring, and Educational Activities

Surveillance and monitoring activities have rapidly evolved in a changing data-driven world, specifically with the rise of public health informatics.⁷¹ Public health surveillance activities are now able to provide scientific data to guide public health decision-making.⁷² Surveillance data can “inform policy changes, guide new proven interventions, sharpen public communication, and help agencies assess research investments.”⁷³ Surveillance can also act as a warning system, track progress of goals, and monitor emerging concerns.⁷⁴ Through the

Resistance, FOOD & DRUG ADMIN. (Jul. 2019), <https://www.fda.gov/animal-veterinary/antimicrobial-resistance/timeline-fda-action-antimicrobial-resistance>.

67. *The State Health Department*, AM. PUB. HEALTH ASS'N (Jan. 1968), <https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/21/09/50/the-state-health-department>.

68. *The State Health Department's Role in the Policy Process*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/injury/pdfs/shd_policy_tool-a.pdf (last visited Mar. 27, 2022).

69. *Public Health Professionals Gateway: 10 Essential Public Health Services*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/publichealthgateway/publichealthservices/essentialhealthservices.html> (March 18, 2021).

70. *Id.*

71. PETER NSUBUGA ET AL., DISEASE CONTROL PRIORITIES IN DEVELOPING COUNTRIES, CH. 53: PUBLIC HEALTH SURVEILLANCE: A TOOL FOR TARGETING AND MONITORING INTERVENTIONS 1000 (2d ed. 2006). “The rapidly evolving field of public health informatics, which deals with collection, classification, storage, retrieval, analysis, and presentation of large amounts of health data, offers the potential for truly integrated public health surveillance based on data standardization, a communications infrastructure, and policies on data access and sharing.” *Id.*

72. *Id.* at 998.

73. *Public Health Surveillance and Data: Service Through Surveillance*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 24, 2018), <https://www.cdc.gov/surveillance/improving-surveillance/Public-health-surveillance.html>.

74. *Health Topics: Surveillance in Emergencies*, WORLD HEALTH ORG., <https://www.who.int/emergencies/surveillance> (last visited Mar. 22, 2022).

use of new data systems, public health experts can begin to harness and react to more data than ever before.⁷⁵ The CDC also provides grants to state and local health departments to support state and local surveillance activities.⁷⁶

Another important aspect of state and local health departments is their educational and community outreach activities. The surveillance and monitoring activities of the state and local health departments can then lead educational activities of state and local health departments. Major services of health departments include professional education and public health education.⁷⁷ These educational functions are incredibly important on the state and local levels due to the close nature of state and local governments to the people.⁷⁸ An important extension of these activities with twenty-first century solutions is PDMPs.

E. Existing Prescription Drug Monitoring Infrastructure

PDMPs are state-run electronic databases that track and monitor prescriptions for controlled substances.⁷⁹ Currently, all fifty states, the District of Columbia, Guam, and Puerto Rico have operational PDMPs.⁸⁰ These programs were implemented as a way to control the opioid epidemic and alter prescriber and patient behaviors around opioids.⁸¹ Through these programs, states can “collect, monitor, and analyze . . . data . . . to support states’ efforts in education, research, enforcement, and abuse prevention.”⁸² Effective PDMPs feature four promising elements: (1) universal utilization by prescribers and pharmacists, (2) real-time data submission by pharmacists, (3) active management by state health departments, and (4) ease of usage and accessibility.⁸³

75. See NSUBUGA ET AL., *supra* note 71, at 997 (explaining that health agencies around the world have started using data during the COVID-19 pandemic to create better public health outcomes).

76. *Public Health Surveillance and Data*, *supra* note 73. “Nearly one third of CDC extramural grant awards and dollars support surveillance related programs, with the majority of support going to state and local health departments.” *Id.*

77. *Education & Training Opportunities*, U.S. DEPT. OF HEALTH & HUM. SERVS., <https://www.hhs.gov/programs/education-and-training/index.html> (March 27, 2018).

78. HODGE, *supra* note 33, at 59–62.

79. *Opioid Overdose: What States Need to Know*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/pdmp/index.html> (May 19, 2021).

80. *PDMP Frequently Asked Questions*, PRESCRIPTION DRUG MONITORING PROGRAM, TRAINING & TECH. ASSISTANCE CTR. (Sept. 2019), <https://www.pdmpassist.org/State> [hereinafter PDMP, *PDMP Frequently Asked Questions*].

81. See *Opioid Overdose: What States Need to Know*, *supra* note 79 (noting that improvements have been made to opioid prescribing by providing data such as patient prescription histories).

82. PRESCRIPTION DRUG MONITORING PROGRAM & TRAINING & TECH. ASSISTANCE CTR., PRESCRIPTION DRUG MONITORING PROGRAM AND MEDICAL EXAMINER/CORONER MEETING 1, https://www.pdmpassist.org/pdf/Resources/PDMP_ME-C_Meeting_Summary_20190703.pdf (last visited Mar. 27, 2022) [hereinafter PDMP, MEDICAL EXAMINER/CORONER MEETING].

83. *Opioid Overdose: What States Need to Know*, *supra* note 79.

Currently, PDMPs monitor controlled substances based on the schedules established by the Federal Controlled Substances Act (CSA).⁸⁴ Each state has autonomy in setting up its PDMP program as it sees fit with differences in various program aspects, such as the time requirements for reporting, who is able to access the data, and other reporting and use requirements.⁸⁵ PDMP best practices include interstate data sharing, integration with health information exchanges, delegate access, user education, and the timeliness of data.⁸⁶ From a public health standpoint, PDMPs can be incredibly useful in the areas of education, epidemiologic surveillance, prevention, and early intervention.⁸⁷ Another promising feature of PDMPs is the ability to send unsolicited reports to prescribers.

1. Unsolicited Reporting Notifications

Unsolicited reporting, a notification to prescribers regarding patients with high utilization of controlled substances, is considered a PDMP best practice.⁸⁸ Unsolicited reporting can serve the following important goals: “informing prescribers and pharmacists that patients may be abusing or diverting controlled substances; helping prescribers make better decisions about prescribing controlled substances, thus improving patient care; and informing potential end users about the PDMP and its value.”⁸⁹ In the context of PDMPs, most of the data provided is solicited, meaning that the prescriber must request the information to see it.⁹⁰ By providing only solicited data, however, there is a wealth of helpful information that is potentially not reviewed or acted upon.⁹¹ To provide this useful information and data to prescribers, there must be an

84. PRESCRIPTION DRUG MONITORING PROGRAM & TRAINING & TECH. ASSISTANCE CTR., PDMP MODEL ACT 2020, at 1, 4 (2020), https://www.pdmpassist.org/pdf/PDMP_Model_Act_2020.pdf [hereinafter PDMP, MODEL ACT 2020].

85. AM. SOC’Y OF ADDICTION MED., PUBLIC POLICY STATEMENT ON PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs) 1 (2018), https://www.asam.org/docs/default-source/public-policy-statements/2018-statement-on-pdmpsf406229472bc604ca5b7ff000030b21a.pdf?sfvrsn=63ba42c2_0 [hereinafter ASAM, PRESCRIPTION DRUG MONITORING PROGRAMS].

86. *Id.*

87. PDMP CTR. OF EXCELLENCE AT BRANDEIS, BRIEFING ON PDMP EFFECTIVENESS 9 (Sept. 2014), <https://dhhs.ne.gov/DOP%20document%20library/PDMP%20Center%20of%20Excellence%20Briefing.pdf> [hereinafter BRIEFING ON PDMP EFFECTIVENESS].

88. PDMP CTR. OF EXCELLENCE AT BRANDEIS, GUIDANCE ON PDMP BEST PRACTICES: OPTIONS FOR UNSOLICITED REPORTING 4 (2014), <https://www.ojp.gov/pdffiles1/bja/247135.pdf/> [hereinafter GUIDANCE ON PDMP BEST PRACTICES].

89. ASS’N. STATE & TERRITORIAL HEALTH OFFS., PRESCRIPTION DRUG MONITORING PROGRAMS: TOOLS FOR EDUCATION, EPIDEMIOLOGICAL SURVEILLANCE, PREVENTION, AND EARLY INTERVENTION 4, <http://www.astho.org/Rx/Brandeis-PDMP-Report/>.

90. FED’N OF STATE MED. BDS., PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs): REPORT AND RECOMMENDATIONS OF THE WORKGROUP ON PDMPs 6 (2018), <https://www.fsmb.org/siteassets/advocacy/policies/prescription-drug-monitoring-programs-adopted.pdf>.

91. *Id.*

underlying analysis of PDMP data “to identify patients meeting criteria for possible inappropriate use[s] of controlled substances or for receiving possibly dangerous quantities and/or combinations of prescription drugs.”⁹² In unsolicited reporting, it is important that false positives—which could reduce the effectiveness of the program—are not over-produced.⁹³ Therefore, a threshold that would trigger a reporting requirement must be established. Unfortunately, among the states that utilize unsolicited reporting, no such consensus on a common threshold has been recognized.⁹⁴ Unsolicited reporting has been found to be beneficial, for example, in Maine, where a substantial portion of the prescribers who received unsolicited reports relating to opioids responded and acted upon the notification.⁹⁵

F. Innovative Uses of PDMP and Other Health Information Exchange Programs

Through the creation of PDMP Programs, various states have also created innovative uses of the PDMP infrastructure with the integration of other health data services. Part II.F. highlights two states and their efforts in the health Information Technology (IT) space: Maryland and Utah.

1. Maryland’s Chesapeake Regional Information System for our Patients (CRISP)⁹⁶

Maryland has established a state-wide Health Information Exchange (HIE) known as “CRISP” which provides a comprehensive, multi-faceted approach to PDMP and various other health data points.⁹⁷ CRISP was designated by the Maryland Health Care Commission as the statewide HIE.⁹⁸ CRISP seeks to foster innovative uses of health data throughout the state through “safer, timelier, efficient, effective, equitable, patient centered care.”⁹⁹ CRISP includes a variety of health information services, including:

92. GUIDANCE ON PDMP BEST PRACTICES, *supra* note 88, at 7.

93. *Id.* at 7.

94. ASS’N. STATE & TERRITORIAL HEALTH OFFS., *supra* note 89, at 4.

95. GUIDANCE ON PDMP BEST PRACTICES, *supra* note 88, at 8.

96. *See generally* MD. CODE ANN., HEALTH–GEN. § 21-2A-01 et seq. (West 2020) (codifying Maryland’s PDMP law and outlining its requirements).

97. CRISP, <https://crisphealth.org/> (last visited Feb. 2, 2022).

98. *PDMP Frequently Asked Questions*, MD. DEP’T OF HEALTH, https://health.maryland.gov/pdmp/Pages/-PDMP_FAQs.aspx (last visited Feb. 2, 2022) [hereinafter MD. DEP’T OF HEALTH, *PDMP Frequently Asked Questions*].

99. *Chesapeake Regional Information System for Our Patients (CRISP)*, JOHNS HOPKINS INST. CLINICAL & TRANSITIONAL RSCH., <https://ictr.johnshopkins.edu/service/informatics> (last visited Mar. 24, 2022).

- (1) Clinical Query Portal, which provides real time clinical information including labs, radiology reports, operative reports, and other clinical notes;¹⁰⁰
- (2) Encounter Notification Service (ENS), which provides real-time alerts to providers when one of their patients is hospitalized;
- (3) PDMP;
- (4) Direct Messaging through CRISP DIRECT, which provides a secure and encrypted e-mail service for health care providers;
- (5) Image Exchange, which provides providers with high-quality radiograph images;
- (6) CRISP Reporting Service, which provides healthcare data and analytics to improve patient care;¹⁰¹ and
- (7) Single Sign-On, which provides integration into medical office software to access CRISP services.¹⁰²

The Maryland CRISP system, through these various programs, shares data with health care providers to facilitate care, reduce costs, and improve health outcomes.¹⁰³

The PDMP program is administered by CRISP and is overseen by the Maryland Department of Health, Behavioral Health Administration.¹⁰⁴ The Maryland PDMP was created to reduce abuse and diversion of prescription drugs.¹⁰⁵ Participation in the Maryland PDMP is mandatory for prescribers and pharmacists.¹⁰⁶

2. Utah's Health Information and PDMP Infrastructure

Like Maryland's use of CRISP, Utah has established comprehensive, linked databases that includes PDMP, All Payer Claims Database, Emergency Department Encounter, and Hospital Inpatient Discharge, among others.¹⁰⁷

100. *Clinical Query Portal*, CRISP, https://www.crisphealth.org/wp-content/uploads/2016/03/Portal-Flyer-Edited-8_16.pdf (last visited Feb. 2, 2022).

101. *CRISP Reporting Services*, CRISP, <https://www.crisphealth.org/applications/crisp-reporting-services-crs/> (last visited Feb. 2, 2022).

102. *See For Patients: What is CRISP?*, CRISP, <https://www.crisphealth.org/for-patients/#what-is-crisp> (last visited Feb. 2, 2022) (discussing integration between hospitals and medical professionals to ease access to clinical information).

103. *Id.*

104. *Maryland Prescription Drug Monitoring Program*, MD. DEP'T OF HEALTH, <https://health.maryland.gov/pdmp/Pages/Home.aspx> (last visited Feb. 2, 2022).

105. *Id.*

106. MD. CODE ANN., HEALTH-GEN. § 21-2A-02(c) (West 2019).

107. *See* COMAGINE HEALTH & UTAH DEPT. OF HEALTH, LEVELS OF CARE FOR TREATING OVERDOSE AND OPIOID USE DISORDER IN UTAH EMERGENCY DEPARTMENTS AND HOSPITALS 3, 10,13 (2020) (describing Utah's efforts to address overdose and opioid use in hospitals). Additional linked data bases

Utah's PDMP (also known as the Controlled Substance Database Program) tracks: morphine milligram equivalents of the patient's current level of opioid use,¹⁰⁸ the number of pharmacies visited in the last month, and if there are any overlapping opioid and benzodiazepine prescriptions.¹⁰⁹ Additionally, Utah has established licensure penalties for failure to register with the program.¹¹⁰

Utah also uses a patient review and restriction program (PRR) to encourage the safe use of opioid prescriptions.¹¹¹ An individual can be identified as at-risk, thereby triggering the program, by satisfying one or more of the following criteria:

- (1) Filling six or more abuse-potential medications in a twelve-month period;
- (2) Utilizing four or more pharmacies in a twelve-month period;
- (3) Visiting: “[f]our or more nonaffiliated primary care providers and/or four or more specialists . . . outside a normal range of utilization in a 12-month period, and/or three or more nonaffiliated providers prescribing abuse-potential medications in a 12-month period”;
- (4) Having “five or more nonemergent emergency department visits in 12-months”;
- (5) Providing cash payments for prescriptions;
- (6) Exhibiting “patterns of early refills or attempted early refills for abuse-potential medications”; or
- (7) Providing “concurrent prescriptions of abuse-potential medications written by nonaffiliated prescribers.”¹¹²

Once a PRR is triggered, patients are required to receive controlled substances from a designated prescriber and pharmacist.¹¹³

include a cancer registry, death and medical examiner reports, the national violent death reporting system, and data relating to continuing medical education completion. *Id.*

108. Morphine Milligram equivalents (MMEs) are “[t]he amount of milligrams of morphine an opioid dosage is equal to when prescribed.” OFF. OF INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUM. SERVS., FACTSHEET: UTAH’S OVERSIGHT OF OPIOID PRESCRIBING AND MONITORING OF OPIOID USE 14 (2019), https://oig.hhs.gov/oas/reports/region7/71805115_Factsheet.pdf/.

109. *Id.* at 6.

110. UTAH CODE ANN. § 58-37f-401(4) (West 2018). These licensure actions include refusing to issue a license, refusing to renew a license, or revocation, suspension, or restriction of an individual’s license. *Id.*

111. PEW CHARITABLE TRS., MEDICAID PROGRAMS THAT IMPROVE THE SAFETY OF OPIOID USE: SPOTLIGHT ON UTAH 1 (2016), https://www.pewtrusts.org/-/media/assets/2016/09/pda_rxastateutah_factsheet-final_updated_927.pdf?la=en&hash=40DD664FF960E5E5FBD59B6B1F2DF641EB1EEE79 [hereinafter PEW CHARITABLE TRS., SPOTLIGHT ON UTAH].

112. *Id.*; see also *Restriction Program*, UTAH DEP’T. OF HEALTH: MEDICAID, <https://medicaid.utah.gov/restriction-program/> (last visited Feb. 2, 2022) (describing prescription restriction requirements for Medicaid enrollees in Utah).

113. PEW CHARITABLE TRS., SPOTLIGHT ON UTAH, *supra* note 111, at 1.

Utah also maintains the Utah Health Information Network (UHIN) which operates the Clinical Health Information Exchange (CHIE).¹¹⁴ The CHIE includes various features such as:

- (1) CHIE Alerts, which provides a notification when patients are admitted or discharged from a hospital or emergency department;
- (2) Direct Secure Messaging, which allows secure communications between healthcare professionals;
- (3) Results Delivery, which provides laboratory, radiology, clinical notes, poison control, and EMS reports; and
- (4) Historical Look-backs, which are triggered when a patient is admitted, discharged, or transferred from a hospital or emergency department and provide an overview the patients previous admissions.¹¹⁵

UHIN works toward securely harnessing healthcare data to create innovative software solutions for the healthcare community.¹¹⁶

III. LEVERAGING PDMPs FOR ANTIBIOTIC TRACKING

This article, while applauding the work that the CDC and other governmental agencies have done, suggests a new state surveillance and education program using the existing PDMP infrastructure. Managing and utilizing state PDMP infrastructure is beneficial since “[s]tates tend to have closer connections to the problems they regulate, which allow them to adapt to local conditions and to improve both compliance and enforcement.”¹¹⁷ States also have authority to regulate in this area.¹¹⁸ Part III.A. begins with a theoretical approach on how surveillance programs could be deployed through PDMP programs.¹¹⁹ Then, Part III.B. discusses the legal approach to implement such a program considering federal and state level requirements.¹²⁰

114. *The CHIE: Clinical Health Information for Providers*, UTAH HEALTH INFO. NETWORK, <https://uhin.org/solutions/providers/chie-providers/> (last visited Feb. 2, 2022).

115. *Id.*

116. *About Us*, UTAH HEALTH INFO. NETWORK, <https://uhin.org/about/> (last visited Feb. 2, 2022).

117. William M. Sage & David A. Hyman, *Combating Antimicrobial Resistance: Regulatory Strategies and Institutional Capacity*, 84 TUL. L. REV. 781, 833 (2010).

118. *See Strategies and Partnerships*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/drugoverdose/policy/index.html> (Apr. 20, 2021) (describing steps states can take to prevent overdoses, including implementing specific laws and improving practices for state programs like Medicaid and worker’s compensation).

119. *See infra* Part III.A.

120. *See infra* Part III.B.

A. Surveillance Programs Through the Use of PDMP

This proposal seeks to broaden the surveillance ability of state and local health departments by expanding upon the existing infrastructure of PDMPs. Since all states and the District of Columbia have existing PDMP programs, the infrastructure for establishing this kind of antibiotic surveillance is already in place.¹²¹ Currently, PDMPs are administered by various state agencies including pharmacy boards, departments of health, professional licensing agencies, law enforcement agencies, and substance abuse agencies.¹²² Various states also track information through their PDMP that is not specific to controlled substance prescribing including: drug-related arrests, drug-related convictions, child welfare case information, criminal court case information, drug court case information, medical marijuana dispensing, naloxone prescription/administration, and overdoses.¹²³ The integration of this additional information within the PDMP software demonstrates the feasibility of extending this software to include antibiotic related prescriptions and data.

Interestingly, one state, Nebraska, currently monitors *all* prescription drugs through their PDMP.¹²⁴ On January 1, 2018, Nebraska began monitoring all dispensed prescriptions so that clinicians could better monitor the care and treatment of their patients.¹²⁵ The shift towards tracking all prescriptions in Nebraska was focused on patient safety and the need for accurate medication reconciliation.¹²⁶ The Nebraska PDMP allows prescribers and dispensers to sort through controlled and non-controlled prescriptions.¹²⁷ Nebraska's comprehensive PDMP provides "10 x more data than traditional PDMP's that include controlled substances only."¹²⁸ Upon implementation from January 1 through June 30, 2018, there were 15,795,016 dispensed prescriptions—90% of these were non-controlled substances.¹²⁹ The enabling statute, while not

121. *State PDMP Profiles and Contacts*, PRESCRIPTION DRUG MONITORING PROGRAM & TRAINING & TECH. ASSISTANCE CTR., <https://www.pdmpassist.org/State> (last visited Feb. 3, 2022).

122. *Id.*

123. See DEPT. OF JUST., BUREAU OF JUST. ASSISTANCE, JUSTICE SYSTEM USE OF PRESCRIPTION DRUG MONITORING PROGRAMS 8–9 (2015) (discussing the intersection between PDMP programs and the criminal justice system).

124. NEB. REV. STAT. § 71-2454(2) (2020).

125. Berie Monegain, *Nebraska Becomes First State to Require All Drugs be Reported to Prescription Monitoring Program*, HEALTHCARE IT NEWS (Jan. 31, 2018, 12:32 PM) <https://www.healthcareitnews.com/news/nebraska-becomes-first-state-require-all-drugs-be-reported-prescription-monitoring-program>.

126. Rachel Balick, *Nebraska Pharmacists Will Report All Prescriptions to State PDMP*, PHARMACY TODAY, Nov. 1, 2017, at 50, 50 [https://www.pharmacytoday.org/article/S1042-0991\(17\)31645-6/fulltext](https://www.pharmacytoday.org/article/S1042-0991(17)31645-6/fulltext).

127. See *id.* (explaining that a new law in Nebraska will compel dispensers to report to the State's PDMP both controlled and non-controlled prescriptions).

128. Alice Middleton & Kevin Borchert, *Nebraska PDMP Case Study*, THE HILLTOP INST., 22 (Aug. 2, 2018) https://mhcc.maryland.gov/mhcc/pages/home/workgroups/documents/electronic_prescription/Nebraska%20Slides_20180802.pdf.

129. *Id.* at 23.

specifically focusing on antibiotics, states a purpose of “allowing prescribers and dispensers to . . . ensure that the prescription drugs are used for medically appropriate purposes.”¹³⁰ Nebraska has gone above and beyond the data requirements advocated for in this article, but for full effectiveness of this proposal, the data also must be acted upon.

1. Establishing a Surveillance Threshold

Since the infrastructure necessary for PDMPs to track antibiotic prescriptions is already in place, the hurdle will be in programming the data tool to identify significant information. To clear this hurdle, a threshold—which will identify the information that is significant enough to trigger an additional review by an expert within the Department of Health—must be established.¹³¹ As with the original PDMP infrastructure, parallels can be made between opioids and the thresholds established for unsolicited reports and PRRs. Upon discussion of these parallels, the following Part concludes with suggested features of a threshold that would be best suited to combat antibiotic resistance.¹³²

a. Parallels to Opioids with Unsolicited Reports

Unsolicited reports can provide prescribers with important, clinically relevant information.¹³³ To send an unsolicited report, the PDMP data must be programmed to identify specific criteria that is suspect of inappropriate use of controlled substances.¹³⁴ Criteria can include actions such as: receiving prescriptions of the same drug type from multiple prescribers or multiple pharmacies in a relatively short period of time, being prescribed higher than a certain number of morphine milligram equivalents, and receiving prescriptions for opioids and benzodiazepines.¹³⁵ For instance, Maine’s regulatory requirements for PDMP-related unsolicited reporting provide that threshold levels may include, but are not limited to, any of the following:

- High number of prescribers in a short period of time as determined by the office;
- High number of doses during a short period of time, as determined by the office;
- Days Supply of prescriptions for the same drug overlapping by more than a few days;

130. NEB. REV. STAT. § 71-2454(1) (2011).

131. *See supra* text accompanying notes 121–123.

132. *See infra* Part III.A.1.a.

133. *See* GUIDANCE ON PDMP BEST PRACTICES, *supra* note 88, at 5 (“A growing body of evidence supports unsolicited reporting as a PDMP best practice.”).

134. *Id.* at 7.

135. *Id.*

- Inappropriate combinations of controlled substances, as determined by the Office;
- More than one method of payment within a short time period;
- More than one out of state prescriber for the same patient, during a short time period, as determined by the Office;
- More than one pharmacy in the same day; or
- More than one pharmacy in different public health districts within one month; and/or Dangerous levels of specific drugs, as determined by the office.¹³⁶

As of April 2022, thirty-seven jurisdictions had PDMP systems that provided unsolicited reports to prescribers,¹³⁷ and twenty-six jurisdictions had PDMP systems that sent unsolicited reports to dispensers.¹³⁸ Among these jurisdictions, there is no consensus as to what triggers a report.¹³⁹ Therefore, in the context of antibiotics, it is important to establish a threshold at which review would be triggered in the State Department of Health for high utilization patients and providers.

b. Parallels to Opioids and PRRs

Also in the context of opioids, PRRs are widely used by Medicaid plans and commercial insurers.¹⁴⁰ Forty-nine state Medicaid plans operate PRRs; Utah is one such jurisdiction.¹⁴¹ These programs, once identifying a patient, restrict their access to controlled substances by limiting their ability to procure controlled substances to a single designated prescriber, pharmacy, or both.¹⁴² The criteria used is largely up to the state's discretion and "var[ies] from [a] simple numeric threshold to an extensive list of criteria that includes a wide variety of behaviors indicative of over-utilization or fraud."¹⁴³ The intent of these programs is to

136. 14-118-11 ME. CODE R. § 9 (2) (LexisNexis 2022). Additionally, upon meeting this threshold, the prescriber and dispenser is notified. *Id.*

137. PRESCRIPTION DRUG MONITORING PROGRAM & TRAINING & TECH. ASSISTANCE CTR., PDMPs AUTHORIZED AND ENGAGED IN SENDING SOLICITED AND UNSOLICITED REPORTS TO HEALTH CARE PROVIDERS AND PATIENTS (2020), https://www.pdmpassist.org/pdf/Health_Care_Entity_Table.pdf [hereinafter PDMP, SOLICITED AND UNSOLICITED REPORTS].

138. *Id.*

139. ASS'N. STATE & TERRITORIAL HEALTH OFFS., *supra* note 89, at 4.

140. *Examining the Opioid Epidemic: Challenges and Opportunities: Hearing Before the S. Comm. of Fin.*, 114th Cong. 2 (2016) (statement of Allan Couckell, Senior Director, Health Programs, The Pew Charitable Trusts).

141. *Id.*; see also *supra* Part II.F.2 (explaining Utah's PRR program).

142. AM. SOC'Y OF ADDICTION MED., PUBLIC POLICY STATEMENT ON PATIENT REVIEW AND RESTRICTION (PRR) PROGRAMS 1 (2016), https://www.asam.org/docs/default-source/public-policy-statements/11-2-public-policy-statement-on-prr-programs---updated.pdf?sfvrsn=5b5d74c2_0 [hereinafter ASAM, PATIENT REVIEW AND RESTRICTION (PRR) PROGRAMS].

143. CTRS. FOR DISEASE CONTROL & PREVENTION, PATIENT REVIEW & RESTRICTION PROGRAMS: LESSONS LEARNED FROM STATE MEDICAID PROGRAMS 3 (2012), <https://www.cdc.gov/drugoverdose/pdf/>

identify those who are at risk of an overdose—based on certain established factors—and ensure that they receive care coordination.¹⁴⁴

c. Suggested Features of a Threshold

While “doctor shopping”¹⁴⁵ is less of a concern with antibiotic prescriptions (than with opioids or other controlled substances), monitoring and surveillance is still essential. As previously demonstrated, not all PDMPs are alike.¹⁴⁶ Thus, it would likely be difficult to achieve a uniform threshold. Nevertheless, suggestions can be made through model legislation.¹⁴⁷ Model legislation has been used in the field of public health as early as 1907.¹⁴⁸ In this context, model legislation should be proposed to create a threshold for triggering review. Using opioids as guidance, the following factors should be considered in the threshold:

- (1) Use of a certain number of antibiotics within a twelve-month period;
- (2) Multiple antibiotic prescriptions by multiple prescribers;
- (3) Use of two or more antibiotics on the WHO’s watch list¹⁴⁹ in a six-month period; and
- (4) Use of any antibiotic which is on the WHO’s reserve list.¹⁵⁰

While it would be challenging to establish a threshold to determine when a particular prescriber is overprescribing, a simple numerical analysis could be conducted to identify the highest prescribers. This identification could then trigger a review which considers other factors such as the prescriber’s specialty and the number of patients he or she typically services. Providers in certain specialties will ultimately produce more antibiotic prescriptions than others simply because of their chosen specialty. However, these providers could be compared to other providers within the same specialty to compare utilization.

PDO_patient_review_meeting-a.pdf [hereinafter CDC, LESSONS LEARNED FROM STATE MEDICAID PROGRAMS].

144. *Examining the Opioid Epidemic: Challenges and Opportunities*, *supra* note 140, at 2.

145. “Doctor shopping” generally refers to “a patient obtaining controlled substances from multiple healthcare practitioners without the prescribers knowledge.” CTRS. FOR DISEASE CONTROL & PREVENTION, PUBLIC HEALTH LAW: DOCTOR SHOPPING LAWS 1 (2012), <https://www.cdc.gov/php/docs/menu-shoppinglaws.pdf> [hereinafter CDC, DOCTOR SHOPPING LAWS].

146. *See generally Maps and Tables*, PRESCRIPTION DRUG MONITORING PROGRAM & TRAINING & TECH. ASSISTANCE CTR., <https://www.pdmpassist.org/content/pdmp-maps-and-tables> (last visited March 2, 2022) [hereinafter PDMP, *Maps and Tables*] (displaying and summarizing PDMPs in different states).

147. Various organizations provide model state legislation on a variety of topics. *See, e.g., About Shared State Legislation*, COUNCIL OF STATE GOV’TS., <https://ssl.csg.org/about/> (sharing state legislation among different states); *see also Current Docket*, AM. ACAD. OF FAM. PHYSICIANS, <https://ssl.csg.org/current-docket/> (presenting model legislation on a variety of topics.).

148. DeKeely Hartsfield et al., *A Review of Model Public Health Laws*, 97 AM. J. PUB. HEALTH. S56, S56 (2007).

149. WORLD HEALTH ORG., *supra* note 13, at 3.

150. *Id.* at 4.

B. Legal Approach

As is evident from the varying natures of PMDP programs across the country, the legal approach to establishing this sort of monitoring system will require a state level legislative approach.¹⁵¹ Nevertheless, federalism requires both federal and state considerations.

1. Federal Level Considerations

The major federal consideration is what sort of support the federal government would be willing to provide to states looking to establish antibiotic tracking programs through PDMP. Since 2016, the CDC AR Solutions Initiative has provided “\$241 million to 57 state and local health departments.”¹⁵² Moreover, federal grants were essential to the original creation of PDMPs through the Harold Rogers PDMP Grant Program administered by the Federal Department of Justice’s Bureau of Justice Assistance.¹⁵³ Since most current federal grants for PDMPs involve substance abuse monitoring, different considerations would arise if federal grants were to be extended to PDMPs for antibiotic resistance and tracking. Another potential federal approach would be to reschedule all antibiotics or certain high-risk antibiotics as Schedule V Substances under the CSA.¹⁵⁴ This could, however, potentially require states to begin tracking antibiotics without state initiative since many state PDMPs track prescriptions based on the Federal Controlled and Dangerous Substances schedule.

2. State Level Considerations

At the state level, there will be three major policy considerations when developing a program for tracking and monitoring antibiotic prescriptions. These considerations include: (1) amending existing PDMP laws; (2) establishing thresholds to trigger review by the state health department; and (3) observing federal and state privacy laws.

151. See PDMP, *Maps and Tables*, *supra* note 146 (displaying the varying nature of different PDMP programs in different states).

152. CTRS. FOR DISEASE CONTROL & PREVENTION, ACTIONS TO COMBAT ANTIBIOTIC RESISTANCE (AR), FISCAL YEAR 2016-2019, <https://www.cdc.gov/drugresistance/pdf/threats-report/CDC-Actions-Combat-AR-508.pdf> [hereinafter CDC, ACTIONS TO COMBAT ANTIBIOTIC RESISTANCE].

153. U.S. DEP’T OF JUST., HAROLD ROGERS PRESCRIPTION DRUG MONITORING PROGRAM FY 2013 COMPETITIVE GRANT ANNOUNCEMENT 1 (2013), <https://bja.ojp.gov/sites/g/files/xyckuh186/files/media/document/BJA-2013-3526.pdf>.

154. Currently eleven jurisdictions only monitor Schedules II-IV, which would mean reclassifying antibiotics into Schedule V would not be tracked in these eleven jurisdictions. PRESCRIPTION DRUG MONITORING PROGRAM & TRAINING & TECH. ASSISTANCE CTR., MANDATORY PDMP ENROLLMENT (2022), https://www.pdmpassist.org/pdf/Mandatory_Enrollment_Conditions.pdf [hereinafter PDMP, MANDATORY PDMP ENROLLMENT].

Since states already have existing PDMPs the authorizing legislation must be amended to include the provision of antibiotics.¹⁵⁵ Alternatively, states could take Nebraska's approach and include all prescription medications. To address these amendments, a state would require support from both chambers of its legislature. Additionally, law and policy concerning the threshold requirement could be established through the legislative process or through agency regulations. Moreover, state legislatures would need to consider federal and state privacy protections, which most PDMPs already include protections for; current PDMP statutes include privacy clauses and penalties for violations of confidentiality.¹⁵⁶ These protections will likely remain if existing PDMP laws are simply amended. Therefore, in order to address these concerns, legislatures would need to ensure that the existing protections apply when amendments are made to include antibiotic tracking.

IV. CONCLUSION

In the age of big data, as antibiotic resistance is growing, it is important to consider the data analytics tools we already have at our fingertips. Through legislative changes to existing PDMP statutes, states could begin tracking their antibiotic prescriptions to anticipate emerging microbial concerns and trends. These new tracking and monitoring programs could allow public health experts to turn the tides in terms of antibiotic resistance. Antibiotics present a paradox: while antibiotic-use is necessary to treat certain illnesses, every use can cause bacteria to evolve, rendering that antibiotic essentially useless.¹⁵⁷ Tracking is a core element of antibiotic stewardship, as defined by the CDC.¹⁵⁸ Through the use of tracking, monitoring and surveillance, state health departments can begin to combat antibiotic resistance within their jurisdictions.

155. See PDMP, *Maps and Tables*, *supra* note 146 (explaining State PDMP programs).

156. MD. CODE ANN., HEALTH-GEN. § 21-2A-04 (b)(9)(i-ii) (West 2019).

157. See LaMontagne, *supra* note 20, at 301 (explaining that the use of antibiotics can create antibiotic resistant bacteria).

158. CDC, THE CORE ELEMENTS, *supra* note 53, at 15.