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Not Quite ‘A New HOPE’—North Carolina’s New Opioid Prescription Monitoring Statute¹

INTRODUCTION

In the time it takes you to read this article, someone in the United States will likely fatally overdose on opioids.¹ Drug overdose deaths have risen dramatically over the last twenty-five years,² prompting the U.S. Department of Health and Human Services to declare the opioid crisis a public health emergency.³ In response, states began creating prescription drug monitoring programs (“PDMPs”) to reduce overprescribing, both by helping prescribers make informed decisions and by helping law enforcement identify deviant prescribers and dispensers.⁴ As of 2017, all fifty states have enacted PDMPs,⁵ though the degree to which physicians are required to use the programs when prescribing opioids varies by state.⁶

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1. See *Understanding the Epidemic*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 19, 2018), <https://www.cdc.gov/drugoverdose/epidemic/index.html> [<https://perma.cc/YG9C-7Q5D>] (stating that more than 130 people die from opioid overdoses every day, or an interpolated rate of approximately one person every eleven minutes).

2. See Josh Katz, *Drug Deaths in America are Rising Faster Than Ever*, N.Y. TIMES (June 5, 2017), <https://www.nytimes.com/interactive/2017/06/05/upshot/opioid-epidemic-drug-overdose-deaths-are-rising-faster-than-ever.html> [<https://perma.cc/DA6D-B43F> (dark archive)] (showing that drug overdose deaths have been steadily rising since 1990).

3. Julie Hirschfield Davis, *Trump Declares Opioid Crisis a ‘Health Emergency’ But Requests No Funds*, N.Y. TIMES (Oct. 26, 2017), <http://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html> [<https://perma.cc/P2M2-F9VR> (dark archive)] (“President Trump on Thursday directed the Department of Health and Human Services to declare the opioid crisis a public health emergency, taking long-anticipated action to address a rapidly escalating epidemic of drug use.”).

4. See John Matthew Butler, William C. Becker & Keith Humphreys, *Big Data and the Opioid Crisis: Balancing Patient Privacy with Public Health*, 46 J.L. MED. & ETHICS 440, 440 (2018) (describing the increasing popularity of PDMPs as a tool to aggregate opioid prescription data: PDMPs enable physicians to better understand patients’ histories with controlled substances and make informed prescription decisions, and allow law enforcement agencies to identify prescribers with higher-than-average—potentially malfeasant—opioid prescription rates); see also, e.g., FLA. STAT. ANN. § 893.055 (2019) (enumerating Florida’s PDMP); KY. REV. STAT. ANN. § 218A.202 (Westlaw through Chapter 201 of the 2019 Regular Session) (enumerating Kentucky’s PDMP); UTAH CODE ANN. §§ 58-37f-101, -201 (Westlaw through 2018 Third Special Session) (enumerating Utah’s PDMP).

5. Austin Huguelet, *Prescription Drug Monitoring Program Gets Long-Awaited Approval in Missouri Senate*, ST. LOUIS POST-DISPATCH (Apr. 13, 2017), https://www.stltoday.com/news/local/govt-and-politics/prescription-drug-monitoring-program-gets-long-awaited-approval-in-missouri/article_5bc2ae1e-294f-5b49-8b52-203e7f0bc098.html [<https://perma.cc/9RH3-F9LV>]

In North Carolina, the rate of overdose deaths nearly doubled between 2010 and 2018,⁷ with several counties reporting overdose death rates ten to nearly twenty times the national average.⁸ Responding to these types of trends in previous years, North Carolina established its own PDMP in 2005, called the Controlled Substances Reporting System (“CSRS”), under the CSRS Act.⁹ As enacted, the purpose of the CSRS is to identify patients who are abusing opioids, reduce overall mortality rates from opioid misuse, and facilitate law enforcement investigation of illicit diversion of opioids.¹⁰ Diversion here refers to illicit or medically unnecessary supply or use of controlled substances that are otherwise legal and medically necessary.¹¹

The CSRS is housed in the North Carolina Department of Health and Human Services and serves as a repository for prescriptions of controlled substances given to “ultimate users” by “dispensers.”¹² An “ultimate user” is any person who lawfully obtains a controlled substance from a dispenser for use in his or her household.¹³ “Dispensers” provide controlled substances to “ultimate users” and are most typically pharmacists.¹⁴ The CSRS Act requires prescribers, typically physicians, to use the CSRS to look at a patient’s prescription history when deciding whether to prescribe

(announcing the Missouri Senate’s passage of its own PDMP and indicating that it is the last state to do so).

6. *PDMP Mandatory Query by Prescribers and Dispensers*, PDMPASSIST.ORG (Jan. 2, 2018), http://www.pdmpassist.org/pdf/Mandatory_Query_20180102.pdf [https://perma.cc/4A9L-PZAZ] (stating that forty states mandate PDMP use to some degree, and fourteen require both prescribers and dispensers to use PDMPs).

7. *North Carolina Opioid Summary: Opioid-Related Overdose Deaths*, NAT’L INST. ON DRUG ABUSE (Feb. 2018), <https://www.drugabuse.gov/opioid-summaries-by-state/north-carolina-opioid-summary> [https://perma.cc/2544-C96J] (“Since 2010, when the rate was 8.1 deaths per 100,000 persons, the rate has almost doubled.”).

8. Forsyth, Guilford, Mecklenburg, and Wake counties report overdose death rates that are in gross excess of the national average of almost twenty-two deaths per 100,000 people. *See North Carolina Drug Overdose Deaths*, COUNTY HEALTH RANKINGS & ROADMAPS (2018), <https://www.countyhealthrankings.org/app/north-carolina/2018/measure/factors/138/data> [https://perma.cc/GUL8-KMMN]; *Opioid Overdose Death Rates and All Drug Overdose Death Rates per 100,000 Population (Age Adjusted)*, HENRY J. KAISER FAM. FOUND. (2017), <https://www.kff.org/other/state-indicator/opioid-overdose-death-rates/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> [https://perma.cc/42EU-ZAF2].

9. N.C. GEN. STAT. § 90-113.70 to -113.71 (2017).

10. *See id.* § 90-113.71(b) (describing legislative purposes of the CSRS Act).

11. PROGRAM EVALUATION DIV., N.C. GEN. ASSEMBLY, NORTH CAROLINA NEEDS TO STRENGTHEN ITS SYSTEM FOR MONITORING AND PREVENTING THE ABUSE OF PRESCRIBED CONTROLLED SUBSTANCES 8 (2014), https://www.ncleg.net/PED/Reports/documents/Rx/Rx_Report.pdf [https://perma.cc/T8JH-2SPY].

12. N.C. GEN. STAT. § 90-113.73 (describing the establishment and maintenance of the controlled substances reporting system).

13. *Id.* § 90-113.72(5).

14. *Id.* § 90-113.72(4).

a controlled substance to the patient.¹⁵ As of 2017, with the enactment of the Strengthen Opioid Misuse Prevention (STOP) Act, dispensers are now also subject to civil penalties if they fail to report prescription data to the CSRS.¹⁶

One important aspect of the CSRS Act was the degree to which it limited law enforcement access to patient data in the CSRS. The statute declared that law enforcement could request data from the CSRS only for a “bona fide specific investigation” that is “related to the enforcement of laws governing licit drugs pursuant to a *lawful court order specifically issued for that purpose*.”¹⁷ Providing judicial oversight of law enforcement access to CSRS data is particularly important because the CSRS houses private medical information.

More recently, in June 2018, North Carolina enacted the Heroin and Opioid Prevention and Enforcement (HOPE) Act, which removed the requirement for a “lawful court order” to release patient prescription data to local law enforcement.¹⁸ While the HOPE Act does require that law enforcement officers only access information pursuant to investigations where there is a “reasonable, good-faith belief based on specific facts and circumstances,”¹⁹ individual officers can construe these standards differently and may be less likely to be as impartial as a judge when deciding whether there is legitimate basis for an investigation.

The HOPE Act also attempted to balance concerns about patient health data privacy in several ways. First, it imposed specific penalties, including civil fines and a private right of action, on law enforcement officers who inappropriately disseminate patient prescription data accessed through the CSRS.²⁰ Second, the HOPE Act required that law enforcement officers become “certified diversion investigators” before they can request

15. *Id.* § 90-113.74C(a) (“Prior to initially prescribing a targeted controlled substance to a patient, a practitioner shall review the information in the controlled substances reporting system . . .”).

16. Strengthen Opioid Misuse Prevention Act of 2017, ch. 74, sec. 10, § 90-113.73, 2017 N.C. Sess. Laws 684, 685, 690–91 (codified as amended at N.C. GEN. STAT. § 90-113.73 (2017)) (establishing “civil penalties for pharmacies that employ dispensers who improperly report information to the controlled substances reporting system (CSRS)”).

17. N.C. GEN. STAT. § 90-113.74(c)(5) (2017) (emphasis added).

18. *Compare* Heroin and Opioid Prevention and Enforcement (HOPE) Act of 2018, ch. 44, § 11.(b), 2018-3 N.C. Adv. Legis. Serv. 21, 28–30 (to be codified at N.C. GEN. STAT. § 90-113.74(c)(5a), (i)) (indicating that CSRS data can also be released to local law enforcement who are designated certified diversion investigators and meet other stated requirements but not requiring a court order), *with* N.C. GEN. STAT. § 90-113.74(c)(5) (requiring a court order pursuant to the active investigation in order to release CSRS data).

19. Heroin and Opioid Prevention and Enforcement (HOPE) Act § 11.(b), 2018-3 N.C. Adv. Legis. Serv. at 29 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90-113.74(i)(7(a))).

20. *See id.* §§ 11.(a), 12, 2018-3 N.C. Adv. Legis. Serv. at 27, 30 (LexisNexis) (to be codified at N.C. GEN. STAT. §§ 90-113.74(k), -113.75(a), (b)).

prescription data.²¹ Certified diversion investigators are defined as “officer[s] affiliated with a qualified law enforcement agency”²² who pass the required “minimum standards” for “certification” under the statute.²³

Notwithstanding incorporation of these balancing measures, removing direct judicial oversight for police access to prescription data has led to an outcry from North Carolina lawmakers, constituents, health organizations, and civil liberties groups.²⁴ Given the contentious nature of using patient prescription data for law enforcement purposes, it will be difficult to resolve this issue in such a way that all concerned parties are satisfied with the solution.

In its current form, the HOPE Act permits law enforcement to access prescription data with little restraint. Given the significance of the privacy interests at stake, and the relative lack of evidence that PDMPs reduce opioid abuse, the North Carolina General Assembly should err on the side of protecting prescription data privacy and amend the HOPE Act accordingly. This analysis proceeds in three parts. Part I sets forth a framework to weigh tradeoffs between privacy imperatives in protecting autonomy and prosecutorial utility of PDMP prescription data. Part II explores privacy issues arising from elements of the HOPE Act’s statutory scheme. Part III aims to mitigate prescription data privacy concerns by proposing amendments that can be implemented even without reinstating the previous court order requirement. Finally, the Conclusion briefly

21. *Id.* § 11.(b), 2018-3 N.C. Adv. Legis. Serv. at 28 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90-113.74(i)(1)).

22. *Id.* § 11.(b), 2018-3 N.C. Adv. Legis. Serv. at 29 (LexisNexis) (to be codified at N.C. GEN. STAT. 90-113.74(i)(7)(a1)).

23. *Id.* §§ 11.(b), 13, 2018-3 N.C. Adv. Legis. Serv. at 28–29, 31 (LexisNexis) (to be codified at N.C. GEN. STAT. §§ 90-113.74(i)(1)(a), -113.74(7)(a1), -113.74E) (allowing release of CSRS data only to law enforcement who have passed the “minimum standards” necessary to become certified diversion investigators, which include training on opioid diversion methods, appropriate CSRS use to identify potential diversion, and basic data privacy).

24. Rashaan Ayesha, *Police Access to Prescription Database Approved in the NC Legislature*, NEWS & OBSERVER (June 15, 2018), <https://www.newsobserver.com/news/politics-government/article213193544.html> [<https://perma.cc/6ZK9-296L> (dark archive)] (“Many House members were supportive of the bill as a whole but criticized the component regarding law enforcement access to the Controlled Substance Reporting System.”); Julie Havlak, *HOPE Act Heads to Governor But Civil Liberties Concerns Remain*, CAROLINA J. (June 15, 2018), <https://www.carolinajournal.com/news-article/hope-act-heads-to-governor-but-civil-libertarian-concerns-remain/> [<https://perma.cc/2K9T-Y3XL>] (indicating Fourth Amendment-based concerns from civil liberties groups and legislative officials due to lack of judicial oversight of the release of CSRS data); Taylor Knopf, *New Opioid Bill Gets Support from Law Enforcement, Concern from Recovery Advocates*, N.C. HEALTH NEWS (June 7, 2018), <https://www.northcarolinahealthnews.org/2018/06/07/new-opioid-bill-gets-support-from-law-enforcement-concern-from-recovery-advocates/> [<https://perma.cc/8DQM-QGXP>] (commenting on objections to the HOPE Act by advocacy groups such as the Addiction Professionals of NC, the NC SUD Federation, and the N.C. Harm Reduction Coalition).

recapitulates the main points from Parts II and III into a coherent map of proposed revisions to the HOPE Act.

I. WEIGHING DATA PRIVACY INTERESTS

Individuals have a strong privacy interest in their own medical information. Patients have no control over the production or documentation of their medical history²⁵ but must necessarily relinquish their personal health information in order to receive quality care.²⁶ Additionally, patients do not control who collects or manages their data—these processes are legally enshrined.²⁷ Given patients’ unique lack of control over their own medical data and the sensitive nature of that data, the law recognizes patients’ right to privacy over their medical data,²⁸ to varying degrees, in nearly all countries.²⁹

Personal medical data is a metric approximation of our visceral selves and is accordingly among the most intimate of private information. Maintaining privacy over medical data is paramount because control over access to personal medical data prevents undue influence by employers, insurers, and other actors seeking to leverage medical data into discriminatory decisionmaking.³⁰ Regulating access to personal medical information, therefore, promotes individual autonomy.³¹ While this interest in autonomy is not an overriding absolute, in cases where the public benefit of granting third-party access is not ascertainable, protecting autonomy should be afforded greater weight because the individual harms resulting from disclosure of personal data are substantial.³² Unauthorized disclosure

25. See Bonnie Kaplan, *Patient Health Data Privacy* 3 (Yale Inst. for Soc’y & Policy Studies, Working Paper No. 14-028, 2014) (stating that medical information is both generated and housed by institutions without the consent of individual patients).

26. *Id.* at 3 (indicating that if an individual seeks quality health care, they must share personal health information).

27. *Id.* (characterizing medical data as distinct from other data because its collection and storage is “legally mandated,” as opposed to simply incentivized privately for the provision of quality care).

28. *Id.* at 5 (“Because of its sensitive nature, separate laws and regulations govern privacy risks of medical records.”).

29. *Id.* at 10.

30. Joy L. Pritts, *The Importance and Value of Protecting the Privacy of Health Information* 4 (2008) (unpublished manuscript), <http://www.nationalacademies.org/hmd/~/media/Files/Activity%20Files/Research/HIPAAandResearch/PrittsPrivacyFinalDraftweb.ashx> [<https://perma.cc/4CE6-KEUJ>].

31. See *id.* at 6.

32. Lawrence O. Gostin & James G. Hodge, Jr., *Personal Privacy and Common Goods: A Framework for Balancing Under the National Health Information Privacy Rule*, 86 MINN. L. REV. 1439, 1441–42 (2002) (“If the data, however, are disclosed in ways that are unlikely to achieve a strong public benefit, and the personal risks are high, individual interests in autonomy should prevail.”).

of medical data can result in personal consequences ranging from social ostracism to reducing an individual's likelihood of pursuing medical treatment due to loss of trust in health care providers.³³ Therefore, any potential public benefit must be weighed against the risk of unauthorized disclosure and intrusion on autonomy. Applying this framework, experts contend the law should prioritize patient autonomy if it is unclear whether the use of PDMPs yield a clear public benefit.³⁴

Importantly, an expansive review of numerous recent studies concludes it is unclear whether PDMPs are effective as a whole.³⁵ While PDMPs have proven effective in certain situations, research suggests these successes are typically confined to a particular constellation of variables: a specific state or geographical area, a specific drug, or a specific PDMP operational structure.³⁶ Variable-specific efficacy of PDMP use may make it difficult to determine the scope of utility even in those states where these programs have been situationally effective because it is potentially difficult to parse the effects of intersecting variables on opioid misuse. More generally, while PDMPs are sometimes effective at slowing increases in opioid misuse, they are not typically effective at decreasing the overall incidence of misuse.³⁷ Additionally, in studies done before all states adopted PDMPs, opioid overdose mortality was not consistently lower in states that had instituted PDMPs.³⁸ Since aggregate data suggests it is at best unclear whether PDMPs are effective, ambiguities should also be construed against PDMP utility. There is no *presumptive* public benefit of PDMP use—the benefit only exists if it can be unequivocally shown.

33. *Id.* at 1448 (“[Medical confidentiality] allows patients to feel comfortable divulging personal information that is often needed for accurate diagnoses and treatment. As explained above, unauthorized uses or disclosures may subject individuals to embarrassment, social stigma, and discrimination.”).

34. *See id.* at 1442.

35. Christopher A. Griggs, Scott G. Weiner & James A. Feldman, *Prescription Drug Monitoring Programs: Examining Limitations and Future Approaches*, XVI WESTERN J. EMERGENCY MED. 67, 67 (2015) (finding that it is hard to determine whether opioid overdose-related death reduction is due to PDMPs, “laws limiting dispensing of medications,” or “overall prescriber awareness of the risks of opioids,” and further indicating that PDMPs have had mixed effects on opioid prescribing); Erin P. Finley et al., *Evaluating the Impact of Prescription Drug Monitoring Program Implementation: A Scoping Review*, 17 BMC HEALTH SERVS. RES., 2017, at 4 (“[T]he extant literature reveals mixed findings about the impact of PDMPs as a tool for reducing misuse and diversion of controlled substances.”).

36. Finley et al., *supra* note 35, at 6 (noting that because the statutory characteristics and implementation of PDMPs vary considerably from state to state, pinpointing which specific features of any given PDMP are responsible for efficacy or the lack thereof is difficult).

37. Liza M. Reifler et al., *Do Prescription Monitoring Programs Impact State Trends in Opioid Abuse/Misuse?*, 13 PAIN MED. 434, 434–42 (2012).

38. Finley et al., *supra* note 35, at 4 (reviewing studies on opioid use-related mortality and finding that there is “no clear pattern of reduced overdose mortality in PDMP states”).

In North Carolina, a recent study found the CSRS is heavily underutilized, with prescribers and dispensers only using the system six percent of the time a prescription is written or filled.³⁹ Another study found that inability to account for key factors bearing on presence or absence of opioid misuse, such as idiosyncratic variations in prescribing practices, makes it difficult to determine efficacy, further confounding analysis of CSRS utility.⁴⁰ Going forward, it may be easier to analyze CSRS utility since the STOP Act enacted a punitive statutory scheme enforcing dispenser reporting.⁴¹ As of yet, however, there is no evidence suggesting that mandating dispenser reporting is *sufficient* to make the CSRS effective.

In summary, applying the PDMP public benefit framework to the expansion of law enforcement CSRS access, the law should prioritize prescription data privacy for two reasons. First, aggregate data suggests CSRS use does not significantly affect rates of opioid diversion. Second, ambiguities due to irregular prescriber reporting make it even more difficult to conclusively show CSRS efficacy. Taken together, it is unclear whether there is a cognizable public benefit from CSRS use by law enforcement that outweighs the harm to individuals resulting from disclosure of a patient's medical information without the patient's consent.

II. PRIVACY ISSUES IN THE STATUTORY SCHEME

Several features of the HOPE Act raise privacy concerns, in part due to the substance of the provisions and in part due to the interplay between different statutory sections. Part A examines two effects of the new statutory penalties under the HOPE Act. First, differences in applying these penalties create perverse incentives for law enforcement officers to solicit data directly from pharmacies as opposed to the CSRS. Second, even if this were not the case, the penalty system incentivizes counterproductive use of prescription data. Part B exposes gaps in coverage by the statutory penalties and analyzes unnecessarily restrictive language that could impede prosecution of future violators of the HOPE Act.

39. PROGRAM EVALUATION DIV., N.C. GEN. ASSEMBLY, *supra* note 11, at 20.

40. See Christopher Ringwalt et al., *The Use of a Prescription Drug Monitoring Program to Develop Algorithms to Identify Providers with Unusual Prescribing Practices for Controlled Substances*, 36 J. PRIMARY PREVENTION 287, 296 (2015) (finding that false positives and negatives are likely to occur because of differences in provider practices and incomplete data).

41. Strengthen Opioid Misuse Prevention Act of 2017, ch. 74, sec. 10, § 90-113.73, 2017 N.C. Sess. Laws 690, 690–91 (codified as amended at N.C. GEN. STAT. § 90-113.73 (2017)).

A. *Privacy Issues Related to Direct Access to Pharmacy Records*

The HOPE Act allows certified diversion investigators (“CDIs”)⁴² to solicit prescription data directly from pharmacies.⁴³ Allowing direct acquisition of pharmacy-derived individual prescription data rather than mandating access exclusively through the CSRS presents potentially perverse incentives for law enforcement to bypass the already limited privacy protections presented in the statutory scheme. This is particularly true given that the statute does not prescribe clear oversight mechanisms for prescription data solicited directly from pharmacies.

Admittedly, it is not unusual for states to statutorily prescribe a right of inspection for administrative agencies to oversee pharmacy recordkeeping.⁴⁴ Most states also allow enforcement officials to inspect pharmacy records for controlled substance regulation purposes.⁴⁵ On the other hand, a 2014 survey found that fewer states allow local law enforcement officers to solicit prescription data directly from pharmacies without a court order.⁴⁶ Nevertheless, acknowledging that a number of states *do* allow local law enforcement to access pharmacy prescription data without a court order,⁴⁷ the HOPE Act’s similar grant of access does not, at first glance, seem indefensible.

The vast majority of states, including North Carolina, also differentiate privacy of prescription data housed in PDMPs from pharmacy records⁴⁸—there are less stringent guidelines for directly accessing prescription data from pharmacies than for prescription data in the CSRS.⁴⁹

42. *See supra* text accompanying notes 21–23.

43. *See* Heroin and Opioid Enforcement and Prevention (HOPE) Act of 2018, ch. 44, § 8, 2018-3 N.C. Adv. Legis. Serv. 21, 23 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90-107.1).

44. *Prescription Monitoring Programs, Pharmacy Records and the Right to Privacy*, NAT’L ALL. FOR MODEL DRUG LAWS 21 (Mar. 2014), <https://namsdl.org/wp-content/uploads/Prescription-Monitoring-Programs-Pharmacy-Records-and-the-Right-to-Privacy.pdf> [<https://perma.cc/K82F-YWWF>] (finding that state PDMPs typically allow access but impose more stringent restrictions on law enforcement access to prescription records without a court order than do the respective state pharmacy statutes).

45. *Id.* (“Every state across the country requires that prescription records be kept by pharmacists, and most allow access to those records to certain officials without a warrant.”).

46. *Id.* at app. B (stating only twenty states allow law enforcement officers access to prescription records housed in pharmacies without a court order authorizing access: Alabama, Alaska, Arizona, Arkansas, California, Florida, Hawaii, Iowa, Maine, Maryland, Missouri, Nebraska, New Hampshire, New York, North Carolina, Ohio, Oklahoma, Tennessee, Vermont, and Washington).

47. *Id.*

48. *Id.* (showing side-by-side comparisons of distinct privacy requirements for pharmacy-derived and PDMP-derived prescription data for all fifty states).

49. *Compare* Heroin and Opioid Prevention and Enforcement (HOPE) Act of 2018, ch. 44, § 11.(b), 2018-3 N.C. Adv. Legis. Serv. 21, 28 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90-113.74(i)(1(d)) (requiring the State Bureau of Investigation to review and approve law

Presumably, this is because prescription data taken directly from pharmacies must be collected incrementally by going from pharmacy to pharmacy.⁵⁰ That process makes it more difficult for unauthorized or malicious users to quickly gain access to multiple patients' records, especially when compared to PDMP use.

The statutory scheme in the HOPE Act, however, potentially creates perverse incentives for CDIs to preferentially solicit prescription data directly from pharmacies rather than from the CSRS because of differences in statutorily and administratively defined punitive measures. The HOPE Act created new statutory penalties for unauthorized access to or disclosure of prescription data;⁵¹ however, the penalties only apply to prescription data in the CSRS.⁵² While the HOPE Act does enact a new section, section 90-107.1, that prohibits CDIs from *disclosing* pharmacy-derived prescription data through channels not "allowed by law,"⁵³ the Act does not affirmatively address unauthorized access.⁵⁴ Moreover, while the HOPE Act clearly prohibits CDIs from improperly disclosing pharmacy-derived prescription data, the Act does not enumerate a statutory penalty for CDIs who do so.⁵⁵

Similarly, the extant statute allowing law enforcement to access pharmacy-derived prescription data prohibits improper disclosure of that data but does not set forth a statutory penalty.⁵⁶ State regulatory agencies also have not promulgated administrative codes defining penalties for improper disclosure.⁵⁷ Failure to expressly define statutory or administrative penalties for improper CDI disclosure of pharmacy-derived prescription data could perversely incentivize the use of section 90-107.1 as

enforcement requests for access to prescription data in the CRS), *with id.* § 8, 2018-3 N.C. Adv. Legis. Serv. at 23–24 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90-107.1) (omitting any requirement that law enforcement seek review or approval by the State Bureau of Investigation before accessing pharmacy-derived prescription data).

50. *See, e.g., Prescription Monitoring Programs, Pharmacy Records and the Right to Privacy, supra* note 44, at 21–22 ("Florida allows law enforcement to go from pharmacy to pharmacy and request and receive copies of patient prescriptions without a warrant, but does not allow law enforcement to have direct access to the prescription monitoring database or to receive information from the database without approval of the program manager . . .").

51. Heroin and Opioid Prevention and Enforcement (HOPE) Act § 11.(a), 2018-3 N.C. Adv. Legis. Serv. at 27 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90-113.74(k)).

52. *Id.*

53. *Id.* § 8, 2018-3 N.C. Adv. Legis. Serv. at 24 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90-107.1(d)).

54. *See id.*

55. *See id.*

56. N.C. GEN. STAT. § 90-107 (2017).

57. *See generally* 10A N.C. ADMIN. CODE 26F (Supp. 2019) (outlining regulations for controlled substances without dedicating any provisions to punitive measures for law enforcement officers that improperly disclose prescription data).

a less scrupulously regulated alternative to the CSRS. Data that would be otherwise inaccessible through the CSRS, due to improper purpose or lack of substantiation of need, could potentially be accessed by going directly to the pharmacies housing the data.

Statutory oversight of pharmacy-derived prescription data is comparatively more limited than that over CSRS data, compounding the problem. While the HOPE Act prohibits CDIs from accessing CSRS data without a formal request to and approval by the State Bureau of Investigation,⁵⁸ the Act institutes unfettered access to prescription data when requested directly from pharmacies.⁵⁹ The State Bureau of Investigation does not prospectively review CDI access of pharmacy-derived prescription data under section 90-107.1,⁶⁰ rather, it only reviews reports of such data retrospectively through random audits.⁶¹ Because there is no prospective or request-based oversight, section 90-107.1 provides law enforcement officials a “backdoor” means to indiscriminately solicit prescription data from pharmacies in a geographic area for a named opioid-diversion suspect even when a similar request to the CSRS might have been denied.

Certainly, soliciting prescription data broadly from pharmacies in an area is somewhat difficult since specific individuals must be named in order to pursue a valid search.⁶² However, because there is no language limiting the scope of inquiry and no requirement of “probable cause” or a similarly stringent evidentiary threshold requisite for investigation, CDIs could feasibly search for a number of individuals in a broad geographical area. Conducting such ostensibly broad searches would still carry a risk to the law enforcement official given the random audits of prescription data accessed directly from pharmacies. Nevertheless, it creates a vehicle for law enforcement to engage in a cost-benefit analysis between overbroad solicitation of prescription data and punishment for potentially inappropriate searching—a decision calculus that forecasts potential abuses of police powers.

58. Heroin and Opioid Prevention and Enforcement (HOPE) Act of 2018, ch. 44, § 11.(b), 2018-3 N.C. Adv. Legis. Serv. 21, 28 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90-113.74(i)(1)(d)) (mandating that “[t]he request has been reviewed and approved by the State Bureau of Investigation”).

59. *See id.* § 8, 2018-3 N.C. Adv. Legis. Serv. at 23 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90-107.1(c)).

60. *See id.* § 8, 2018-3 N.C. Adv. Legis. Serv. at 23 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90-107.1(b)).

61. *Id.* § 8, 2018-3 N.C. Adv. Legis. Serv. at 23 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90.107(a)(5)).

62. *Id.* (requiring that the investigating CDI provide the “first name, last name, and date of birth” for individuals whose prescription data is sought).

Even taken in the light most favorable to the statute, wherein CDIs only request data from pharmacies for named opioid-diversion suspects in a particular geographic area, acquiring prescription data under section 90-107.1 is at best inefficient because it requires CDIs to iteratively and indiscriminately inspect all the pharmacies in a given area. Other states have solved this problem. For example, Kentucky's PDMP (called "KASPER")⁶³ is one of the most effective in the country.⁶⁴ Over the last two decades, KASPER implementation has moved Kentucky from second-highest to thirty-first in rate of nonmedical use of prescription painkillers.⁶⁵ Kentucky law enforcement officials have been able to use de-identified data from PDMPs to pinpoint hotspots and communities most at risk.⁶⁶ This approach requires data directly from the PDMP and arguably relies on law enforcement officials *not* soliciting prescription data from individual pharmacies to avoid generating piecemeal and potentially misrepresentative data sets. By contrast, in addition to creating a backdoor channel for improper solicitation of prescription data, such access to North Carolina prescription data under section 90-107.1 also disincentivizes uses of the CSRS that might stand a greater chance of benefiting the mission of law enforcement officials.

Although disavowal of the court order requirement for local law enforcement CSRS access does not disrupt the traditional dynamic of lesser protections afforded to pharmacy-derived prescription data, the HOPE Act's dissimilar statutory penalty schemes for these two vehicles of access facilitate abuses of police powers. Explicit statutory penalties (or regulatory penalties promulgated by the State Bureau of Investigation) for CDIs who improperly disclose pharmacy-derived prescription data would help address this issue.

63. See KY. REV. STAT. ANN. § 218A.202 (Westlaw through Chapter 201 of the 2019 Regular Session) (laying out Kentucky's "[e]lectronic system for monitoring controlled substances").

64. See *Pennsylvania Looks to Upgrade Prescription Drug Monitoring Program*, INST. FOR RES., EDUC. & TRAINING IN ADDICTIONS (June 21, 2013), <https://ireta.org/resources/pennsylvania-looks-to-upgrade-prescription-drug-monitoring-program/> [<https://perma.cc/VQP8-WNS4>] (indicating that Kentucky's PMDP is considered a "gold standard").

65. *Id.* ("Kentucky has seen its ranking among states with the highest nonmedical use of prescription painkillers drop from second to thirty-first place, reflecting a drop that officials attribute largely to its monitoring program.").

66. *Prescription Drug Monitoring Programs: A Guide For Healthcare Providers*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. 1, 6 (2017), <https://store.samhsa.gov/system/files/sma16-4997.pdf> [<https://perma.cc/D63B-X2EU>] (indicating that state departmental health officials can use de-identified aggregate PDMP data to determine which communities present the greatest need for, and the opportunity for greatest benefit from, opioid treatment and prevention programs).

B. Ineffective Language Hamstrings CSRS-Related Penalties

The HOPE Act establishes a penalty for *indirectly* accessing CSRS data that is inadequate to protect against potential abuse of police powers. A recent case from the Tennessee Court of Appeals, *Brumley v. City of Cleveland* (“*Brumley II*”),⁶⁷ illustrates the gap in the law. In *Brumley II*, two members of a regional drug task force approached the plaintiff, Police Officer Brumley, with suspicions that the task force director “might be abusing prescription medications.”⁶⁸ In an unrelated judicial proceeding, the presiding judge informed Officer Brumley that the task force director “appeared to be under the influence” while in chambers.⁶⁹ Officer Brumley subsequently asked his neighbor, a pharmacist, to look up the task force director’s prescription drug history in the state PDMP.⁷⁰ Officer Brumley found no evidence of prescription abuse.⁷¹ More importantly, he was subsequently terminated, in part because he violated state law and departmental policy by soliciting PDMP data prior to opening an active investigation pursuant to the matter.⁷² However, after affirming the trial court’s ruling of summary judgment against Officer Brumley,⁷³ the Tennessee Court of Appeals, in *Brumley III*, ultimately reversed the grant of summary judgment against Officer Brumley on grounds that there was a genuine question of fact as to whether the city legally terminated him.⁷⁴ As part of its analysis, the court considered testimony of other officers in the department (previously rejected as inadmissible in lower court proceedings) about how case facts are often examined preliminarily before opening an active investigation.⁷⁵

67. No. E2012-00002-COA-R3-CV, 2013 WL 1737860 (Tenn. Ct. App. Apr. 23, 2013) [hereinafter *Brumley II*].

68. *Id.* at *1.

69. *Id.*

70. *Id.*

71. *Id.*

72. *Id.* at *2.

73. *Id.* at *2, *7.

74. No. E2014-02213-COA-R3-CV, 2015 WL 6000551, at *7 (Tenn. Ct. App. Oct. 15, 2015) [hereinafter *Brumley III*] (“Considering the evidence in the light most favorable to Plaintiff, as we are constrained to do, we conclude that there was material evidence from which the trier of fact *could* conclude that Plaintiff’s employment was terminated solely for his refusal to remain silent about Chief Snyder’s alleged illegal actions. Accordingly, we further conclude that the trial court erred in dismissing the complaint at this point in the proceedings because material questions of fact remained.”).

75. *Id.* at *2 (referring to testimony of another officer in the department who stated “that it was not common practice for officers to open a case file and inform their superior officers of criminal investigations that are in the early preliminary stage”).

This is disconcerting—Tennessee’s confidentiality provisions at the time of *Brumley* required a case number for PDMP use,⁷⁶ as is currently true in North Carolina.⁷⁷ Despite soliciting a pharmacist in order to circuitously access PDMP data without a case number, Officer Brumley’s actions, hypothetically, might have been permissible had there been a strong enough case that he was acting in accordance with local law enforcement regulations. This case raises two further concerns. First, administrative codes or departmental policies should be promulgated by local law enforcement departments to ensure safeguards under the HOPE Act are effective. Second, statutory felonies for CDIs who access or disclose prescription data “from the system for a purpose not authorized”⁷⁸ may be insufficient in scope to adequately protect patient privacy.

Departmental codes would help curb the risk of CDIs improperly accessing or disclosing prescription data. Although the court in *Brumley III* did not find dispositive the expert testimony regarding divergent procedures for initiating investigations, at minimum the court indicated such evidence should be considered.⁷⁹ If police officers are allowed to raise such de facto defenses to statutorily or departmentally prescribed processes designed to protect citizens’ privacy interests, the department protocols should be explicitly written to avoid usurping legislative intent.

This is no mere question of administration, thus little deference need be given to the departments. Whether officers adhere to the requirement for an active case investigation before using the CSRS, or solicit pharmacists to access CSRS data and circumvent statutory privacy protections, is a question that lies at the heart of the statute. Additionally, since departmental officials are best poised to directly oversee the actions of CDIs, it is prudent to empower departmental policies to facilitate oversight. Therefore, local law enforcement should take extraordinary care to ensure that their departmental protocols are clearly defined and reflect the processes and privacy safeguards reflected in the statute.

Expanding the scope of statutory protections against improper access or disclosure of prescription information is equally important. Statutory

76. TENN. CODE ANN. § 53-10-306(b) (Westlaw through the 2019 First Reg. Sess.) (“When requesting information from the database, law enforcement personnel shall provide a case number as part of the process for requesting information from the database. The case number entered shall correspond with an official investigation involving controlled substances and information requested should directly relate to the investigation.”).

77. Heroin and Opioid Prevention and Enforcement (HOPE) Act of 2018, ch. 44, § 11.(b), 2018-3 N.C. Adv. Legis. Serv. 21, 30 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90-113.74(j)(2)(a)).

78. *Id.* § 11.(a), 2018-3 N.C. Adv. Legis. Serv. at 27 (LexisNexis) (to be codified at N.C. GEN. STAT. 90-113.74(k)(2)).

79. *See Brumley III*, 2015 WL 6000551, at *2.

penalties created under section 90-113.74(k) of the HOPE Act apply primarily to accessing data “from the [CSRS]” for a “purpose not authorized by [section 90-113.74].”⁸⁰ Under section 90-113.74, the relevant permissible statutory purpose is “for investigative or evidentiary purposes related to violations of State or federal law.”⁸¹ This specified purpose may be overbroad—CDIs can investigate *any* case rationally related to a concern about controlled substance issues without violating the statute. Although there are some protections for confidentiality of prescription data built into extant legislation,⁸² there is little recourse for unsavory methods used to acquire information.

Furthermore, the only portion of section 90-113.74 criminalizing *indirect* access to prescription information in the CSRS requires that the individual have “willfully and maliciously obtain[ed], disclose[d], or disseminate[d] prescription information . . . and with the intent to use such information for commercial advantage or personal gain, or to maliciously harm any person.”⁸³ Because of the conjunctive “and” in the statute, willful and malicious actions can only be prosecuted under the statute if they *also* involve use of prescription information for “commercial advantage,” “personal gain,” or to “maliciously harm.”⁸⁴ However, delimiting potential “willfully and maliciously” taken actions to these three categories shackles the statute’s ability to safeguard against impropriety outside of this narrowly defined scope. In fact, other North Carolina statutes felonizing willful or malicious actions typically do not exhibit such extensive conditioning of the mental state,⁸⁵ possibly to provide prosecutorial flexibility in bringing a case forward. All penalties under section 90-113.74 are already detrimentally limited to “purpose[s] not authorized”⁸⁶ by the statute. Further restricting the scope of punishable actions taken “willfully

80. Heroin and Opioid Prevention and Enforcement (HOPE) Act § 11.(a), 2018-3 N.C. Adv. Legis. Serv. at 27 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90-113.74(k)).

81. N.C. GEN. STAT. § 90-113.74(a) (2017) (“[E]xcept as otherwise provided below [CSRS data] may only be used (i) for investigative or evidentiary purposes related to violations of State or federal law . . .”).

82. *See id.* (stating that “prescription information shall not be disclosed or disseminated to any person or entity by any person or entity authorized to review prescription information,” but failing to describe any statutory penalty if this provision is violated).

83. Heroin and Opioid Prevention and Enforcement (HOPE) Act § 11.(a), 2018-3 N.C. Adv. Legis. Serv. at 27 (to be codified at N.C. GEN. STAT. § 90-113.74(k)(3)) (emphasis added).

84. *Id.*

85. *See, e.g.*, N.C. GEN. STAT. § 14-49 (2017) (declaring that “[a]ny person who willfully and maliciously injures another by the use of any explosive or incendiary device or material is guilty of a Class D felony” but not including language further delimiting the mental state); *id.* § 14-163 (“If any person shall willfully and unlawfully poison any horse, mule, hog, sheep or other livestock, the property of another, such person shall be punished as a Class I felon.”).

86. Heroin and Opioid Prevention and Enforcement (HOPE) Act § 11.(a), 2018-3 N.C. Adv. Legis. Serv. at 27 (to be codified at N.C. GEN. STAT. § 90-113.74(k)).

and maliciously” unduly weakens statutory safeguards against improper CDI use of CSRS prescription data.

III. AMENDING THE HOPE ACT TO SAFEGUARD PRIVACY

Amending the HOPE Act can facilitate safeguarding of prescription data privacy, even without reimplementing the previous court order requirement. In this section, I propose two amendments to accomplish this goal. First, the North Carolina General Assembly should import existing language from the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) to restrict the scope of CSRS information given to law enforcement officials to the scope canonically applied to the same context under HIPAA. Second, it should enumerate a statutory right to patient revision of prescription drug records in the CSRS.

A. *Limiting the Scope of Accessed Information*

While the HOPE Act does require the State Bureau of Investigation to approve CDI requests to access CSRS data,⁸⁷ the Act would benefit from language limiting the scope and nature of the requested information. In particular, the Act lacks language restricting access to unrelated patient information or limiting the scope of prescription data to immediate needs of an “active investigation.”⁸⁸ Instead, the HOPE Act relies on a punitive statutory scheme to deter inappropriately expansive sweeps of patient prescription and personal data.⁸⁹ As indicated in Part II, there are numerous issues surrounding the scope of implementation of these provisions and their ability to safeguard privacy interests.⁹⁰ Therefore, restricting information access at the outset is more likely to be effective than relying on punitive measures to deter indiscriminate access to medication data.

Nearly half of the North Carolina House of Representatives similarly wanted to restrict initial data access; their opinion was made apparent during final debate on the HOPE Act.⁹¹ Representative Robert Reives (D-Sanford) proposed an amendment that would require local law enforcement

87. *Id.* § 11.(b), 2018-3 N.C. Adv. Legis. Serv. at 28 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90-113.74(i)(1)(d)).

88. The requirement that the request be “reasonably related to a bona fide active investigation” only relates to the relevance of the requested information, not the type of personal data or the scope of prescription data to be granted. *See id.* § 11.(b), 2018-3 N.C. Adv. Legis. Serv. at 28 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90-113.74(i)(1)(c)).

89. *See id.* § 11.(a), 2018-3 N.C. Adv. Legis. Serv. at 27 (LexisNexis) (to be codified at N.C. GEN. STAT. § 90-113.74(k)).

90. *See supra* Section II.A.

91. *See* S.B. 616, amend. A5, Gen. Assemb., 2017–2018 Sess. (N.C. 2018) (amending § 90-113.74(i) to include a “court order” requirement for CDI access to the CSRS, but failing to pass the North Carolina Senate on a 48-55 vote).

to obtain a court order before accessing prescription data, as had been the case under the STOP Act, but the amendment narrowly failed to pass with a vote of forty-eight in favor and fifty-five against.⁹² Support for the amendment largely fell along party lines but did include several Republican members like Representative Michael Speciale (R-New Bern), who pointed out that “[t]he issue is not whether this bill is needed . . . but [that] it oversteps itself when it allows the government to look at private records without a warrant.”⁹³ Similarly, Representative David Rogers (R-Rutherfordton) pointed out that removal of the requirement for a warrant or court order is problematic because the “reasonable, good faith” standard is ambiguous, and “what to one officer may be reasonable, to a judge is completely unreasonable.”⁹⁴ Pushback against the amendment focused primarily on the need for a prompt response to law enforcement requests for data access, with Representative Gregory Murphy (R-Greenville) and others emphasizing the need to act quickly, contending that under current law “it takes five to seven days to get a judge to sign off on something.”⁹⁵

As it stands, the HOPE Act prioritizes the perceived need for a prompt response over ensuring law enforcement officials do not access more prescription data than is reasonably needed for an active investigation. This is particularly problematic given the lack of compelling evidence showing that PDMPs are effective at reducing opioid diversion rates, as discussed in Part I. Under the framework established in Part I, requiring a court order for access to prescription data, as was the standard under the CSRS and STOP acts,⁹⁶ would be the ideal safeguard to protect data privacy, and therefore patient autonomy. The General Assembly could look to other states, most recently Utah, that have reverted from a warrantless standard to a “court order” standard without issue.⁹⁷

If reverting to a “court order” standard remains politically intractable, however, consensus might more easily be leveraged to incorporate unambiguous language limiting dissemination of medication data to what is *reasonably necessary* for pursuing the active investigation. This is not

92. *Id.*

93. Taylor Knopf, *Debate Over New Opioid Bill Dragged on Through the Night*, N.C. HEALTH NEWS (June 14, 2018), <https://www.northcarolinahealthnews.org/2018/06/14/debate-over-hope-act-dragged-on-through-the-night/> [https://perma.cc/693M-Y2R5].

94. *Id.*

95. *Id.*

96. N.C. GEN. STAT. § 90-113.74(c)(5) (2017); *see* Strengthen Opioid Misuse Prevention Act of 2017, ch. 74, sec. 11, § 90-113.74, 2017 N.C. Sess. Laws 684, 691–92 (codified as amended at N.C. GEN. STAT. § 90-113.74 (2017)) (leaving § 90-113.74(c)(5) unaltered).

97. *Want to Use Utah’s Drug Database? Get a Warrant*, STANDARD-EXAMINER (Dec. 17, 2015), https://www.standard.net/opinion/our-view/want-to-use-utah-s-drug-database-get-a-warrant/article_25b07725-68e3-58ed-8f90-ae357e718ddf.html [https://perma.cc/6NYM-CXB8].

unprecedented. HIPAA, the federal statute regulating privacy of protected health information, specifically addresses the appropriate scope of medical data to be released to law enforcement.⁹⁸ Under HIPAA, releasing medical data to law enforcement without a court order requires a showing that: (1) “[t]he information sought is relevant and material to a legitimate law enforcement inquiry”; (2) “[t]he request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought”; and (3) “[d]e-identified information could not reasonably be used.”⁹⁹ The U.S. Department of Health and Human Services has further validated this standard in administrative documents produced by the agency.¹⁰⁰

Adopting HIPAA standards to limit the scope of prescription data available for an active investigation does not violate statutory intent. Under the HOPE Act, CDIs must be certified by undergoing training on a variety of topics related to drug diversion and prescription data; among other requirements, the statute expressly includes “[d]ata privacy and security provisions of [HIPAA] and other pertinent federal and State laws governing privacy and security of confidential data and records.”¹⁰¹ Although law enforcement is not itself a “covered entity” bound by HIPAA,¹⁰² inclusion of HIPAA privacy provisions in mandatory training for CDIs suggests statutory intent to adhere to the framework of HIPAA protection of medical information.

Other states have taken similar stances.¹⁰³ For example, Delaware’s PDMP statute delimits the scope of PDMP information available to law enforcement using language essentially identical to that in HIPAA.¹⁰⁴ Access to PDMP data may be granted to law enforcement officials “provided that such information be relevant and material to such investigation, limited in scope to the extent reasonably practicable in light

98. 45 C.F.R. § 164.512(f)(1)(ii)(C) (2018).

99. *Id.*

100. *See Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule: A Guide for Law Enforcement*, DEP’T OF HEALTH & HUMAN SERVS. 2, https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/emergency/final_hipaa_guide_law_enforcement.pdf [<https://perma.cc/4FMK-6NWZ>].

101. Heroin and Opioid Prevention and Enforcement (HOPE) Act of 2018, ch. 44, § 14.(b), 2018-3 N.C. Adv. Legis. Serv. 21, 32 (LexisNexis) (to be codified at N.C. GEN. STAT. § 17E-4(a)(14)(g)).

102. *See* 45 C.F.R. § 160.103 (2018).

103. *See, e.g.*, DEL. CODE ANN. tit. 16 § 4798(l)(2)(d) (Supp. 9 2018); LA. STAT. ANN. § 40:1007(F)(3) (Westlaw through 2018 Third Extraordinary Session) (allowing release of PDMP data without a court order if requirements identical to those enumerated under HIPAA in 45 C.F.R. § 164.512(f)(1)(ii)(C) are met).

104. *See* DEL. CODE ANN. tit. 16 § 4798(l)(2)(d).

of the purpose for which the information is sought, and include identifying information only upon a showing of need.”¹⁰⁵

Incorporating similar language in the HOPE Act would help alleviate the concerns of lawmakers like Representative Rogers that ambiguous “good faith” standards requiring the prescription data be “reasonably related” to the investigation create an unworkable standard for even conscientious law enforcement officials.¹⁰⁶ Using specific language would directly restrict inappropriate prescription data access, rather than proximately relying on deterrence from laws punishing improper use of the data. Moreover, incorporating this type of language into the statute would not change the process proposed by the HOPE Act, so it would not sacrifice any expedience prioritized by the law. While restoring a court order requirement would be the ideal solution to protect data privacy, unambiguous statutory language limiting type and scope of medication data accessed would provide some privacy safeguards and has a better chance of generating consensus in the North Carolina General Assembly.

B. *Allowing Revision of Personal CSRS Records*

Because HIPAA regulations do not bind the CSRS, state law should explicitly prescribe privacy protections for CSRS data, including the right for individuals to amend their CSRS records. HIPAA applies to “covered entit[ies]”—consisting of health plans, health care providers, and health care clearinghouses—and their “business associate[s].”¹⁰⁷ Prescribers and pharmacists are HIPAA-covered entities, so inputting prescription data into the CSRS is subject to HIPAA regulation.¹⁰⁸ However, the CSRS itself is neither a HIPAA “covered entity” nor a related “business associate,” so once CSRS data is entered into the system, it is no longer subject to HIPAA regulation.¹⁰⁹ State governments are, however, free to enumerate “privacy and security requirements” under state law.¹¹⁰ Therefore, the General

105. *Id.*

106. *See* Knopf, *supra* note 93.

107. 45 C.F.R § 160.103.

108. LISA N. SACCO, JOHNATHAN H. DUFF & AMANDA K. SARATA, CONG. RESEARCH SERV., R42593, PRESCRIPTION DRUG MONITORING PROGRAMS 27 (2018), <https://fas.org/sgp/crs/misc/R42593.pdf> [<https://perma.cc/L9B7-8XN2>] (“PDMPs also receive protected health information (PHI) from pharmacists and other health care providers (HIPAA covered entities) who are subject to the federal HIPAA Privacy Rule.”).

109. *Id.* at 28 (“A PDMP is not a HIPAA covered entity, nor is it generally a business associate[, so] . . . the HIPAA requirements and standards for maintaining the security and privacy of the [protected health information] . . . that apply to HIPAA covered entities would not apply to PDMPs.”).

110. *Id.* (“Although HIPAA may not apply, privacy and security requirements for PDMPs are still enumerated under state law.”).

Assembly has not only the privilege, but the *prerogative* to enact privacy protections for CSRS data.

Although CSRS data is not subject to HIPAA regulation, explicit references to HIPAA in mandatory CDI trainings suggest statutory intent to comport to HIPAA standards,¹¹¹ including the right for patients to revise mistakes in their prescription histories. Under HIPAA, patients have a “right to . . . amend protected health information or a record about the individual.”¹¹² The entity housing the protected health information reserves the right to deny the revision request if the records are accurate,¹¹³ and there are also relevant exceptions, such as prohibiting revision of records that are under investigation for criminal activity.¹¹⁴ By carving out important exceptions while allowing requests to amend patient medical records, HIPAA evenly balances governmental (particularly prosecutorial) and private interests regarding the right to revise protected health information.

Not allowing patients the right to revise potential mistakes in CSRS data, particularly when patients do not get a choice as to whether their data is included in the CSRS,¹¹⁵ heavily impinges on patient autonomy. Under North Carolina law, patients are allowed to view their records in the CSRS,¹¹⁶ but there is no statutory or administrative grant of a right to amend.¹¹⁷ The right to amend is particularly important because merely being “under investigation” for opioid misuse can irrevocably impact lives, even if individuals under investigation are later exonerated.¹¹⁸ Given the

111. See *supra* text accompanying notes 101–05.

112. 45 C.F.R. § 164.526(a)(1) (2018).

113. *Id.* § 164.526(a)(2) (“A covered entity may deny an individual’s request for amendment, if it determines that the protected health information or record . . . [i]s accurate and complete.”).

114. *Id.* § 164.524(a)(1) (“[A]n individual has a right of access to inspect and obtain a copy of protected health information about the individual . . . except for . . . [i]nformation compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.”).

115. Strengthen Opioid Misuse Prevention Act of 2017, ch. 74, 2017 N.C. Sess. Laws 684, 685 (mandating reporting of prescription data by prescribers and dispensers).

116. See N.C. GEN. STAT. § 90-113.74(c) (2017) (“The Department shall release data in the controlled substances reporting system to . . . [a]n individual who requests the individual’s own controlled substances reporting system information.”).

117. While *prescribers* have the right to correct their prescribing history, nowhere is it written that *patients* have a right to correct their prescription history. See *NC Controlled Substance Reporting System (CSRS)*, N.C. DEP’T OF HEALTH & HUMAN SERVS., <https://www.ncdhhs.gov/divisions/mhddsas/ncdcs/csrs> [https://perma.cc/QX4Y-P7Q3]. Additionally, the patient form for requesting CSRS data does not include any reference to an amendment or correction process. See *Request for Individual’s Own Controlled Substances Reporting System Information*, N.C. DEP’T OF HEALTH & HUMAN SERVS., <https://files.nc.gov/ncdhhs/documents/files/csrs-individualreq10-18.pdf> [https://perma.cc/NCA2-NGF3] (last updated June 2010).

118. Mark Greenblatt & Angela M. Hill, *Exclusive Investigation: Your Prescriptions Aren’t Private*, WCPO CINCINNATI (Aug. 30, 2016), <https://www.wcpo.com/longform/so-you-think->

devastating effects of an investigation predicated on faulty information, and since HIPAA standards prevent the amendment process from impeding law enforcement activities, the balance of equities between privacy and prosecutorial utility favors explicitly importing the HIPAA “right to amendment” for CSRS data.

CONCLUSION

While addressing the opioid crisis is of utmost importance, doing so need not come at the cost of individual privacy, particularly by sacrificing privacy of medical information. As it stands, the HOPE Act presents risk of serious harms to individual privacy. While the HOPE Act was designed to facilitate the investigative process by allowing law enforcement officers to access CSRS data without a court order, analysis of PDMP programs at large shows it is unclear whether PDMPs are effective. Given the inconclusive evidence of their efficacy, and the lack of evidence that the statutory regime in the HOPE Act would make the CSRS more effective, protecting privacy of prescription data should accordingly be granted greater weight, particularly since the harms of disclosing private medical information without consent are well established.¹¹⁹

Amending the HOPE Act can significantly improve prescription data privacy. While reinstating the court order requirement for accessing the CSRS would provide the most protection of privacy, several alternative amendments could at least partially protect privacy interests. First, the General Assembly should establish clear statutory penalties for improper use of pharmacy-derived prescription data, and local law enforcement agencies should establish regulatory penalties to the same end. Second, the General Assembly should expand the scope of felonies created to deter inappropriate use of CSRS data or remove overly constraining language defining the mental state requirements for these felonies. Third, the General Assembly should adopt HIPAA standards requiring that CSRS data accessed pursuant to an active investigation is only shared to the extent reasonably necessary to aid the enforcement efforts. Fourth, the General Assembly should adopt HIPAA standards allowing patients to amend any inaccuracies in their prescription history. The General Assembly adopting these measures would go a long way towards restoring faith in the North Carolina government’s management of sensitive data that, perhaps more than any other, lies at the heart of who we are as individuals.

prescriptions-are-private [<https://perma.cc/39AK-KAGD>] (finding that an investigation based on faulty evidence delayed a couple from adopting a child and nearly resulted in termination of both suspects’ employment in the city fire department).

119. See Gostin & Hodge, *supra* note 32, at 1142.

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