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Report to the Legislature on Act 205,
Sec. 3 - Report Relating to 18 V.S.A. § 4218
December 15, 2006

VERMONT
DEPARTMENT OF HEALTH
Agency of Human Services

108 Cherry Street, PO Box 70
Burlington, VT 05402
802-951-1258
healthvermont.gov

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Executive Summary

In accordance with ***Act 205,*** Section 3, the Commissioner of the Department of Health (VDH) provides this report "regarding revisions to 18 V.S.A. § 4218 which will address medical privacy concerns that may be raised by permitting law enforcement unfettered access to pharmacy records." [1]

This report was prepared in consultation with the commissioner of public safety (DPS), the executive director of states attorneys and sheriffs (SAS), the defender general (DG), and the executive director of the Vermont chapter of the American civil liberties union (ACLU), or their designees.

In summary, this report includes a description by DPS of the current implementation of section 4218, and a joint statement of VDH and DPS, with which SAS concurs, and separate statements of the ACLU and DG assessing the medical privacy concerns and the interaction of section 4218 and the federal Health Insurance Portability and Accountability Act (HIPAA).

VDH, DPS and SAS conclude that section 4218 is a useful tool for law enforcement and that pharmacies may only disclose information pursuant to that statute if the disclosure is compliant with HIPAA. Therefore, any medical privacy concerns are addressed by HIPAA and no revision of section 4218 is necessary.

The ACLU of Vermont believes that the 1960s state statute, 18 V.S.A. § 4218, should be repealed and that access to prescription records held in pharmacies be governed by the provisions of the federal Health Insurance Portability and Accountability Act (HIPAA). If 18 V.S.A. § 4218 is not repealed, the ACLU believes that the state is required to seek a determination from the federal Secretary of Health and Human Services that 18 V.S.A. § 4218 preempts HIPAA. Further, if 18 V.S.A. § 4218 is not repealed, the ACLU believes that the law's immunity provision should be removed or revised.

The DG agrees with the ACLU that 18 V.S.A. § 4218(b) and (c) should be repealed for the reasons that the ACLU has asserted, but also because the statute is overbroad and lacking in any standards to guide or curtail law enforcement.

[1] The text of 18 V.S.A. § 4218, as amended by Act 205, is appended to this report for ease of reference.

Current Implementation of 18 V.S.A. § 4218

DPS Statement

The primary provisions of 18 V.S.A. § 4218 examined for this report provide in pertinent part that "the department of public safety, its officers, agents, inspectors, and representatives, and pursuant to its specific authorization any other peace officer within the state, and of all state's attorneys," and "their specifically authorized agents shall have, at all times, access to all orders, prescriptions, and records kept or maintained under this chapter, as provided herein." 18 V.S.A. § 4218(a) and (b). Chapter 84 of Title 18 specifies the records, including those related to the manufacture, prescribing and dispensing of controlled substances, that must be kept by pharmacies and other health care providers that are subject to access by authorized law enforcement pursuant to section 4218. Therefore, for purposes of this report it is understood that the description in Section 3 of Act 205 of "unfettered access to pharmacy records" refers only to those pharmacy records created and maintained relating to controlled substances as required by Chapter 84.

According to Commissioner Sleeper, deaths attributed to illegal use or abuse of pharmaceutical drugs (regulated by Chapter 84 of Title 18) represent the majority of drug-related deaths in Vermont that have occurred over the past several years. This trend is of great concern to the Commissioner, and, in his opinion, represents a serious public safety threat. Last year, the legislature enacted S. 90. It did so presumably in response to its recognition of the gravity of the problem, as was testified to by members of VDH, DPS and the health care community. S. 90 was designed to create a database of health information that enables VDH and the health care community to more readily identify the misuse or abuse of pharmaceutical drugs and to intervene with a therapeutic response. In short, S. 90 created prevention and treatment tools for use by the health care community. The database and its monitoring program were not created as investigative tools for use by law enforcement. In fact, with the acquiescence of Commissioner Sleeper, S. 90 specifically prohibits law enforcement direct access to the information in the database. This was due, in part, to the recognition that law enforcement did not need another investigative tool given the existence of Chapter 84 of Title 18. With the passage of S. 90, Vermont law now provides for prevention, treatment and investigative tools that, used together, may minimize or potentially eliminate the dangerous misuse and abuse of pharmaceutical/prescription drugs.

The provisions of 18 V.S.A. § 4218 have been an effective tool in enforcing Chapter 84 of Title 18, thereby minimizing the public safety harm resulting from the misuse and abuse of pharmaceutical drugs. Commissioner Sleeper bases his opinion on his experience. Commissioner Sleeper has been a member of the DPS for 29 years. During his tenure, he supervised and was a member of the

drug task force. He also received specific training as a drug diversion officer. According to Commissioner Sleeper, the ability of the diversion officer to immediately access specific pharmaceutical records in response to a concern that a person is abusing and/or diverting prescription drugs has and will continue to save lives and prevent harm.

Commissioner Sleeper reports that during his 29 years of service at DPS he is not aware of one example when law enforcement used section 4218 as a means of randomly, and without cause, examining pharmaceutical records.[2] In addition, he is not aware of any complaints or expressions of concern indicating that the sought information was improperly utilized (i.e. for other than criminal investigation into an alleged diversion case). Commissioner Sleeper also reports that over the past 29 years the only officers authorized by DPS to investigate matters through section 4218 of Title 18 are drug diversion officers.

Section 4218 states that access to records (maintained pursuant Chapter 84) is limited to DPS officers, officers authorized by DPS and the state's attorneys. Local law enforcement and other officers cannot seek to access pharmacy records pursuant to section 4218 unless authorized by DPS. In practice, and over the 29 years of the Commissioner's service at DPS, DPS has restricted its authorization to a specifically trained group of investigators known as drug diversion officers. The Commissioner is not aware of any state's attorney who has directly sought access to these records. He believes that it is the practice of state's attorneys and local law enforcement to seek access of pharmacy records (directly from the pharmacies) through diversion officers. The Commissioner states that there are approximately fifteen State Police diversion investigators that have been trained in pharmaceutical investigations and all of them work those cases on a part time basis dependent upon incoming complaints.

Diversion officers receive training that equips them to deal with the unique issues raised by the misuse or abuse of prescription drugs. They work closely with and rely upon the expertise of pharmacists and physicians. Currently, diversion officers, pharmacists and physicians train with and to each other in an effort to

[2] Years ago, diversion investigators did occasionally conduct a general search of pharmaceutical records when they were aware that controlled substances from pharmacies were being diverted into a particular community, but did not know who the source of the drugs was or what pharmacy dispensed the drugs. DPS would argue that such access was with cause. In such cases the investigators were able to review paper records looking for a pattern that would point them to a suspect. Even then however, the investigators began their search with relevant pharmacies (i.e., pharmacies in communities affected or nearby by geographic area of concern). With the demise of paper records and the creation of HIPAA such a search is either no longer possible or extremely difficult to conduct. See first full paragraph 2 of page 6 for an explanation of the impact of electronic databases and pages 7-9 for a discussion on the impact of HIPAA and the obligation of health care provider to make sure that HIPAA permits disclosure for a particular health record. In any event, the Commissioner is not aware of a recent example of such a generalized search having occurred and believes that current practice is as described in this section.

identify and intercept the illegal misuse of prescription drugs. As a law enforcement tool, diversion officers have used section 4218 to identify people who have illegally diverted or abused controlled substances (pharmaceuticals). Time is often a crucial factor in those circumstances; a speedy response is necessary to protect the community or specific individuals from the illegal distribution of such controlled substances. In DPS' view, any delay could deprive diversion officers of the ability to intervene in time to prevent the illegal diversion and use of controlled substances. Illegal use of controlled substances presents a significant risk to the community and may result in serious bodily injury or death.

According to Commissioner Sleeper, diversion officers only access pharmacy records pursuant to section 4218 in response to a specific complaint or information of a possible violation of law. Section 4218 is not used in an unfettered manner to search randomly through records looking for possible crimes. Generally, diversion officers receive information concerning illegal drug use involving prescriptions from a pharmacist or physician.[3] When a diversion officer does seek access to pharmacy records, he/she only accesses patient-specific information related to the complaint and does not conduct a more general review of pharmacy records. This practice is also a function of the electronic databases now used by the pharmaceutical industry. Databases, unlike paper records, can only be accessed by password and a person can only view what is on the screen, usually one record at time. As matter of practice, it is the pharmacist who pulls up a specific record for the officer to view.[4]

Finally, diversion officers and state's attorneys do not execute their duties in a vacuum. Vermont is small community and its law enforcement officers and state's attorneys serve many masters: the public, municipal authorities, and the legislative, executive and judicial branches. This oversight also serves as a check to the behavior of law enforcement and state's attorneys. There are many examples of occasions where law enforcement and state's attorneys have, in their discretion, elected not to exercise a power granted to them in order to avoid doing something that would offend the public or its governing bodies. In addition to the constant oversight provided by Vermont's community and its governments, DPS officers must abide by statute, case law, DPS policies and the Vermont State Police Code of Conduct. Failure to do so results in consequences that may include criminal and civil liability and/ or dismissal from employment. State's Attorneys are subject to the same laws and cases, as well as the Rules of Professional Conduct for Attorneys. Failure to do so results in consequences that may include civil liability and/or dismissal from the practice of law. It is for these reasons that the Commissioner believes that DPS and the state's attorneys have employed a practice that has been implemented without complaint for at

[3] Less frequently, the complaint comes from another entity or person such as another law enforcement officer or a school.

[4] An exception to this may be when it is the pharmacist who is suspected of violating Chapter 84.

least 29 years. This history demonstrates that the access granted to certain law enforcement officers and to the state's attorneys to records maintained under Chapter 84 is not unfettered.

Assessment of Medical Privacy Concerns

The VDH and DPS Position

VDH and DPS examined the application of the privacy protections of the Health Insurance Portability and Accountability Act (HIPAA) to the pharmacy records which would be subject to disclosure pursuant to section 4218. HIPAA applies to covered entities and defines the circumstances under which protected health information may be disclosed. DPS is not a covered entity under HIPAA and is not subject to HIPAA. Pharmacies are covered entities and are subject to the provisions of HIPAA. The issue then is whether a covered entity, such as a pharmacy, is permitted by HIPAA to disclose protected health information at the request of a law enforcement officer pursuant to Title 18 section 4218. VDH and DPS conclude that there are circumstances under which HIPAA permits a pharmacist to disclose protected health information pursuant to section 4218 of Title 18 and therefore that state law is not contrary to HIPAA.

HIPAA does permit health care providers to disclose protected health information to law enforcement under certain circumstances, including some circumstances authorized by section 4218. For example, HIPAA permits a pharmacist to disclose protected health care information to DPS when the pharmacist has a good faith belief that the disclosure is necessary to prevent or lessen a serious and imminent threat and that the disclosure is to a person reasonably able to lessen the threat. 45 C.F.R. § 165.512(j). HIPAA also permits a pharmacist to disclose protected health information to DPS when the pharmacist believes in good faith that the protected health information constitutes evidence of criminal conduct that occurred on the premises of the pharmacy. 45 C.F.R. § 164.512(f)(5). Pursuant to HIPAA, the covered entity, i.e. pharmacist, is the person or entity responsible for determining whether HIPAA permits disclosure of protected health information. In the event that a state law authorizes or compels disclosure of protected health information and such a provision conflicts with HIPAA, the covered entity is also responsible for resolving that conflict through HIPAA.

HIPAA requires a covered entity to create and retain certain records relating to disclosures of protected health information and must provide an accounting of disclosures of protected health information for a period covering up to a maximum of six years prior to the individual's request. 45 C.F.R. § 164.528. While HIPAA permits a covered entity to temporarily suspend an individual's right

to receive such an accounting when requested by an oversight agency or law enforcement official, the records of the disclosures must be kept and provided following the temporary suspension period as provided in 45 C.F.R. § 164.528(a)(2). Therefore, this provision of HIPAA does require that records of disclosures made to law enforcement pursuant to section 4218 and HIPAA must be kept by the covered entity.

HIPAA contemplates that state laws may conflict with its terms and has been written to address those situations. HIPAA, by its terms, preempts provisions of state law that are contrary to HIPAA, unless state law affords greater privacy protection. When state law affords greater protection than HIPAA, the state law is not preempted and the covered entity must follow state law.
HIPAA regulations provide that a state statute is "contrary" to HIPAA if it is impossible for the covered entity to comply with both HIPAA and the state law or if the state law stands as an obstacle to the accomplishment of the full purposes and objectives of HIPAA. 45 C.F.R. § 160.202. Applying this standard, conflicts between HIPAA and section 4218 of Title 18 must be resolved by the covered entity on a case-by-case basis. The pharmacy, as a covered entity, must determine whether HIPAA permits the requested disclosure to DPS, and that determination will depend on the circumstances of the request for the protected health information. As in the examples above, there are circumstances where complying both with HIPAA and section 4218 would not be impossible and the disclosure would be permitted.

In the event the pharmacist determines that HIPAA does not permit the disclosure, he/she is required by HIPAA to refuse disclosure. Since HIPAA would preempt state law in this case, section 4218 of Title 18 would not control and the pharmacist would not be in violation of section 4218 for refusing to disclose.

For these reasons, VDH and DPS conclude that section 4218 is not contrary to HIPAA. Correspondingly, since the pharmacies are bound by HIPAA and may disclose information only as permitted by HIPAA, any medical privacy concerns are addressed by HIPAA and no revision of section 4218 is necessary.

Since the passage of HIPAA in 1996, pharmacists in Vermont have been dealing with the question of whether disclosure pursuant to 4218 of Title 18 is permitted under HIPAA. DPS and VDH believe that it is notable that concerns regarding section 4218 of Title 18 were raised by the ACLU, and not the pharmacists[5] or individuals whose health care records are at issue.

[5] DPS general counsel recalls that in 2006 a representative or member of the Board of Pharmacy testified before the Senate Judiciary Committee regarding law enforcements' access to health records and investigations under Chapter 84 of Title 18 (the bill at issue was Senate 90). It is the recollection of DPS counsel that the testimony, in essence, was that Vermont pharmacists had no concerns regarding the access law enforcement has to its records pursuant to section 4218.

The ACLU would like to repeal the immunity section of 4218 (Title 18 section 4218(c)) in order to subject covered entities to HIPAA's enforcement provisions. DPS and VDH believe that a covered entity is subject to HIPAA penalties/fines/liabilities if the entity violated HIPAA. Section 4218(c) affords no protection to a covered entity that violates HIPAA. This is so because under such circumstances section 4218(c) conflicts with HIPAA's enforcement mechanism and therefore is preempted by HIPAA. In other words, for any conflict that may exist between state law (section 4218(c)) and HIPAA, HIPAA controls.

The SAS Position

SAS supports the positions and arguments of VDH and DPS as stated herein.

The ACLU Position

During discussion of S. 90 (which became Act 205), the Legislature heard testimony regarding medical privacy concerns because of the access to pharmacy records given to law enforcement officials pursuant to 18 V.S.A. § 4218. Act 205 established a committee to study the issue and report back to the Legislature with an analysis of 18 V.S.A. § 4218's impact on medical privacy and recommendations, if any, for changes in the law. The federal Health Insurance Portability and Accountability Act (HIPAA) comes into play because – as a federal law – it supercedes state law, except in some limited circumstances. (18 V.S.A. § 4218 was passed by the Vermont Legislature in 1967, HIPAA by Congress in 1996.) Much of the concern about medical privacy centers on whether the privacy rights guaranteed individuals under HIPPA are being observed – specifically, because of laws such as 18 V.S.A. § 4218.

The ACLU of Vermont believes that the 1960s statute, 18 V.S.A. § 4218, should be repealed and that access to prescription records held in pharmacies be governed by the provisions of the federal Health Insurance Portability and Accountability Act (HIPAA). HIPAA is a more modern, and a much more comprehensive, law that takes into account privacy issues and concerns that have arisen since 18 V.S.A. § 4218 was enacted 40 years ago. Law enforcement has stated that its use of 18 V.S.A. § 4218 is infrequent, and that when the law is used that they employ a decision-making process that follows procedures anticipated in HIPAA. Given this, there seems no current need for 18 V.S.A. § 4218 to remain on the books. Additionally, pharmacists should not have to struggle with reconciling two different laws in making decisions around access to private medical records.

If 18 V.S.A. § 4218 is not repealed, the ACLU believes that the state needs to obtain from the federal Secretary of Health and Human Services a determination that the contrary state law meets the criteria specified in HIPAA to allow it to be followed (rather than HIPAA). HIPAA, by its terms, preempts contrary provisions of state law, unless state law affords greater privacy protection. When state law affords greater protection then HIPAA, HIPAA provides that state law controls.

The ACLU of Vermont believes section 4218 is contrary to and therefore pre-empted by HIPAA. The conflict between the two laws is this: HIPAA *permits* disclosure of pharmacy records for law enforcement purposes while 18 V.S.A. § 4218 *requires* disclosure of pharmacy records to law enforcement.[6] HIPAA offers Vermonters a higher degree of privacy than 18 V.S.A. § 4218 because it gives covered entities the freedom to disclose, or not to disclose, protected health information. State law does *not* give covered entities that choice and, in effect, removes one of the checks and balances that exists in HIPAA to protect the privacy of individuals' medical records.

VDH asserts that 18 V.S.A. § 4218 is not contrary to HIPAA because HIPAA permits a pharmacist, under certain circumstances, to disclose protected health information to law enforcement officials. The ACLU disagrees with this reasoning. HIPAA *does* permit disclosure of pharmacy records when the pharmacist has a good-faith belief that the disclosure constitutes evidence of criminal conduct that occurred on the premises of the pharmacy[7] and when the pharmacist has a good-faith belief the disclosure is necessary to prevent or lessen a serious and imminent threat and the disclosure is to a person reasonably able to lessen the threat.[8] However, these are situations in which a pharmacist may *on his or her own initiative* disclose protected health information to law enforcement officials. These provisions do not cover situations in which law enforcement officials seek disclosure of protected health information. Therefore, these provisions do not apply to situations in which Vermont law enforcement officials would seek disclosure under 18 V.S.A. § 4218.

Although "Commissioner Sleeper reports that during his 29 years of service at DPS he is not aware of one example when law enforcement used section 4218 as a means of randomly, and without cause, examining pharmaceutical records",

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[6] 18 V.S.A. § 4218 provides that law enforcement officers "shall have, at all times, access to all orders, prescriptions, and records kept or maintained under this chapter, as provided herein." 18 V.S.A. § 4218(a) and (b). HIPAA provides, "A covered entity *may* use or disclose protected health information…in the situations covered by this section…" 45 C.F.R. §164.512 (specifying uses and disclosures for which an authorization or opportunity to agree or object is not required)(emphasis added).

[7] 45 C.F.R. § 164.512(f)(5)

[8] 45 C.F.R. § 165.512(j)

there is nothing in the language of 18 V.S.A. § 4218 that would prevent DPS from doing so. In this way, 18 V.S.A. § 4218 also conflicts with HIPAA, which only allows disclosure of records for purposes of specific investigation.

Additionally, if 18 V.S.A. § 4218 is not repealed, the ACLU feels that the immunity provision should be removed, or at the least revised. Law enforcement has asserted that the law is not misused. Given that, there is no reason to extend blanket immunity to those involved in access issues. The ACLU feels that it is not too much to ask that applicable state and federal laws designed to protect individuals' privacy be followed. HIPAA states that covered entities will not be sanctioned for responding in good faith to legal process and reporting requirements; however, it imposes civil and criminal penalties for failure to comply with HIPAA. The ACLU feels that this strikes an appropriate balance between efforts taken in good faith and those where greater care and deliberation should have been taken.

The Defender General Position

The Defender General agrees with the ACLU that 18 V.S.A. § 4218(b) and (c) should be repealed for the reasons that the ACLU has asserted, but also because the statute is overbroad and lacking in any standards to guide or curtail law enforcement. Furthermore, there is no need for the statute as pharmacists must comply with HIPAA. HIPAA governs the pharmacists disclosure of records, whereas §4218 permits law enforcement's unfettered access to these records.

The DG agrees that the specific standards embodied in HIPAA, 45 C.F.R. § 165.512(j) embody a clear and reasonable standard similar to what the Legislature recently enacted in 18 V.S.A. § 4284. These standards permit a pharmacist to disclose protected health care information to DPS in two important instances: (1) when the pharmacist has a good faith belief the disclosure is necessary to prevent or lessen a serious and imminent threat and the disclosure is to a person reasonably able to lessen the threat, and (2) when the pharmacist believes in good faith that the disclosure constitutes evidence of criminal conduct. 45 C.F.R. § 164.512(f)(5).

This is similar to a reasonable suspicion standard and provides protection against unfettered law enforcement access. The Commissioner of Public Safety apparently agrees that police officers should have "cause" to inspect pharmacy records, as he asserts that he is not aware of any instances where officers did inspect records without some form of cause: "Commissioner Sleeper reports that during his 29 years of service at DPS he is not aware of one example when law enforcement used section 4218 as a means of randomly, and without cause, examining pharmaceutical records." Public Safety simply wants to retain full

discretion to decide what that cause may be and when police have it. Police officers, individuals, pharmacists, and judges may differ on what constitutes "cause."

HIPAA spells it out more clearly. Furthermore, because pharmacists must comply with HIPAA, the onus is on individual pharmacists to determine whether HIPAA or § 4218 applies to a particular request by law enforcement. Given that, it seems reasonable to follow the dictates of HIPAA which require a minimal showing of reasonable suspicion that the records contain evidence of a crime or that disclosure must be made to avert an imminent threat of harm. Rather than risk the conflict between HIPAA and state law, repeal of § 4218(b) will make it clear that the simple standards of HIPAA control. That way, the police, the public and pharmacists will be equally protected. Since Public Safety states that it is generally complying with such a standard, no hardship will be imposed upon the agency, while the benefit to the public of knowing that they are protected from unfettered police access to their private records will be great.

Conclusion

ACLU Conclusion Statement

The creation of this study committee grew out of the Legislature's concerns over the privacy of individuals' prescription drug records. These concerns came to light in 2005, during the development of S. 90, which proposed to create an aggregated computerized state prescription drug database. Specifically, the concern was whether existing law permitting law enforcement access to pharmacy records (18 V.S.A. § 4218) would also give law enforcement officers access to a statewide computerized drug database.

The Legislature resolved its privacy concerns with respect to S. 90 by including language in the final bill that specifically prohibits law enforcement access to the database.[9] However, the Legislature remained concerned about the privacy

[9] The development of S. 90 was more complex than portrayed by the Department of Public Safety in the "Implementation" section of this report. We apologize for adding to the length of this report by including details of the passage, but we feel it is important to have a clear record of the bill's difficult history.

The Legislature enacted S. 90 (the bill became Act 205) in response to both law enforcement and health concerns over use of prescription drugs. The bill was introduced in 2005; attempts to pass it then, including an attempt to add it to the health care reform bill, failed when the ACLU and others raised concerns that 18 V.S.A. § 4218 might allow law enforcement the same access to an aggregated computerized state prescription drug database as law enforcement currently has to individuals' prescription drug records held in pharmacies. DPS did not dispute that it would seek this access. The Legislature wished to have these privacy concerns addressed. It took up the bill again in 2006, after discussions among numerous parties in the off-session.

implications of 18 V.S.A. § 4218. In passing Act 205, the Legislature created the committee that is submitting this report, and appointed specific stakeholders as members. The charge to the committee was to review 18 V.S.A. § 4218 and make recommendations, if any, for revisions "which will address medical record privacy concerns that may be raised by permitting law enforcement unfettered access to pharmacy records."

Recommendations By The ACLU

1. The ACLU recommends that 18 V.S.A. § 4218 be repealed because it does not adequately protect the privacy of individuals' pharmaceutical records. The ACLU disagrees with the determination by VDH and DPS (in the "Conclusion" section of this report) that 18 V.S.A. § 4218 does not permit law enforcement "'unfettered access' to pharmacy records." In its statement regarding the current implementation of the law, DPS states in Footnote 2:

> *Years ago, diversion investigators did occasionally conduct a general search of pharmaceutical records when they were aware that controlled substances from pharmacies were being diverted into a particular community, but did not know who the source of the drugs was or what pharmacy dispensed the drugs. DPS would argue that such access was with cause. In such cases the investigators were able to review paper records looking for a pattern that would point them to a suspect.*

This information shows that law enforcement has in the past felt that 18 V.S.A. § 4218 does indeed provide them with the opportunity of "unfettered access" to pharmacy records. Law enforcement has, according to DPS Commissioner

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A great number of people testified about the database before the Senate Judiciary Committee and the House Human Services Committee in 2006, giving different reasons for its utility or expressing concerns about its use. Those testifying included representatives of VDH and DPS, emergency room physicians, pharmacists, pain management specialists, a Vermont Medical Society representative, a State Pharmacy Board representative, patients who had become addicted to pain medications, and privacy advocates including the ACLU. The problems identified ranged from "doctor-shopping" to "doctor-firing" to "over-prescribing" to illegal diversion of prescription drugs. The committees spent many hours sorting through legitimate health needs of patients in great need of pain medication, prescription errors physicians can make, the need for doctors to be able to feel that they can exercise professional judgment to serve their patients' best interests without having to worry they will be targeted for criminal investigation, to privacy concerns of patients, doctors, pharmacists, hospitals, advocates, or others. Deliberations were not easy.

The opening statement of Act 205 recognizes that the Legislature's chief intent in passing the bill was "to promote the public health through enhanced opportunities for treatment for and prevention of abuse of controlled substances, without interfering with the legal medical use of those substances." In short, Act 205 created prevention and treatment tools for use by the health care community.

Sleeper, simply not chosen in recent years to avail itself of this opportunity. And VDH and DPS do note in the "Assessment of Medical Privacy Concerns" section of the report that "authorized law enforcement and state's attorneys have elected not to use 4218 to its fullest extent as a matter of general practice." However, not utilizing the opportunity does not negate the opportunity itself. Further, no court decision against "unfettered access" has been issued that would suggest such access is prohibited.

It is important, too, to point out that in the "Implementation" section, the list given of law enforcement officers who may access individual pharmacy records under 18 V.S.A. § 4218 is not complete. The DPS Statement says, "Section 4218 states that access to records (maintained pursuant to Chapter 84) is limited to DPS officers, officers authorized by DPS and the state's attorneys." The statutory language of 18 V.S.A. § 4218 is broader, however: "It is hereby made the duty of the department of public safety, its officers, agents, inspectors and representatives, and pursuant to its specific authorization any other peace officer within the state, and of all state's attorneys, to enforce all provisions of this chapter…." Although "agents, inspectors, and representatives" of the DPS are not defined in the statute, it is DPS's position that "local law enforcement and other officers cannot seek to access pharmacy records pursuant to section 4218 unless authorized by DPS." However, with no apparent records kept of pharmacy records access, it is unclear if this has in fact been the practice over the 40 years the law has been in existence.

DPS ability to enforce Chapter 84 of Title 18 would not be diminished if the Legislature repeals the specific section, § 4218. Any legitimate access that law enforcement needs to individuals' private medical records, including prescription drug records, is covered by the federal HIPAA law. There is no statistical evidence to support the claim by DPS in the "Implementation" section that "the provisions of 18 V.S.A. § 4218 have been an effective tool in enforcing Chapter 84 of Title 18…." The claim is an opinion offered by Commissioner Sleeper based "on his experience" of 29 years with the department. There appear to be no records concerning the implementation – effective or ineffective, proper or improper – of 18 V.S.A. § 4218 over its 40-year history.

2. If § 4218 is not repealed, the ACLU believes that the state is required to seek a determination from the Secretary of Health and Human Services that § 4218 preempts HIPAA. The ACLU believes § 4218 and HIPAA are in conflict and that therefore, under the terms of HIPAA, HIPAA should control because it affords greater privacy protection than § 4218. Without a determination by the Secretary that the state may rely on § 4218, the ACLU believes the state's continued adherence to § 4218 violates federal law.
The ACLU and the Defender General agree that there are important differences between the language in HIPAA *permitting* a pharmacist to turn over an individual's prescription drug records, and the language in 18 V.S.A. § 4218

requiring pharmacists to do so. The DPS and VDH contend that since HIPAA "would pre-empt state law in this case," a pharmacist could refuse to disclose the records. If this is the case, there is no utility to 18 V.S.A. § 4218. Its only utility would be if a pharmacist were ignorant of HIPAA protections and responsibilities, and assume that he or she must comply with a request by police for access to an individual's pharmacy records. In this case, the pharmacist might then unwittingly assume liability for misjudging his/her responsibilities, and the privacy rights of patients. The mere presence of the state law, in other words, could result in the pharmacist breaking the federal law and being held liable. This is not right, and is not fair to pharmacists. The remedy is to repeal 18 V.S.A. § 4218 so pharmacists are not forced to resolve inconsistencies between the state and federal law.[10]

3. The ACLU recommends that if § 4218 is not repealed, the immunity provision should be removed, or at least revised. DPS has asserted that the law is not misused. The ACLU wishes to respectfully note the fragile and sometimes tenuous nature of the "oversight and watchful eyes of the public" that VDH and DPS point to as checks against abuse of power in utilization of the provisions of 18 V.S.A. § 4218. We note the state's unfortunate experience of misconduct by officers of the law and of ineffective oversight by local and state officials, attorneys, the press, juries and judges in the Paul Lawrence police drug scandal of the early 1970s. As Hamilton Davis wrote in his book about Officer Lawrence's practices, *Mocking Justice*: "The American system assumes that if the policeman and the prosecutor and the judge and the jury, working in an adversary system, do their jobs with a normal amount of intelligence and honesty and courage, then justice will be done – injustice will be rare. That almost certainly is not the case. The system is exquisitely fragile, as demonstrated here."

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[10] Footnote 5 in the "Assessment of Medical Privacy Concerns" section of this report gives the mistaken impression that "Vermont pharmacists had no concerns regarding the access law enforcement has to its records pursuant to section 4218." In fact, on numerous occasions, pharmacists, and the advocate for the pharmacists' professional organization, testified that they had great privacy concerns about law enforcement access to pharmacy records – either through records in pharmacies or through an aggregated state prescription drug monitoring database. On March 30 before the House Human Services Committee, pharmacist Jeffrey P. Firlik (who has practiced in Vermont about 20 years and had recently been appointed to the state Board of Pharmacy) testified to privacy concerns arising from legitimate use of pain medication. He specifically worried about access to pharmacy records that 18 VSA § 4218 gives law enforcement. On April 6, Anthony Otis of the pharmacists' professional organization, Vermont Pharmacists Association, testified to the same committee that pharmacists don't want to be "traffic cops"; they don't want to have to weed out suspicious activities. James Marmar, a Woodstock pharmacist and president of the Vermont Pharmacists' Association, told the committee that in New Hampshire a bill similar to S. 90 didn't even get out of committee because of privacy concerns. Dr. Evan Musman, a pain management specialist from South Burlington, testified that "we're all afraid of big brother." He said that on the national level, doctors and pharmacists – not police and medical boards – are the ones most expected to access prescription drug records because the main interest of such records is pain management and better health.

A law that does not contain the usual safeguards against unreasonable searches, a law that is outdated and either conflicts or is superseded by federal law in its application, a law where abuse of closely held privacy rights is possible, should not remain on the books. It is for these reasons that the ACLU believes the Legislature should repeal 18 V.S.A. § 4218.

VDH and DPS Conclusion Statement

VDH and DPS do not believe that section 4218 permits law enforcement "unfettered" access to pharmacy records. First, section 4218 authorizes only DPS officers, DPS designated law enforcement and state's attorneys to enforce provision of Chapter 84 and to access certain pharmacy records. Second, the pharmacy records that may be accessed are limited to those records kept or maintained pursuant to Chapter 84 as specified in 4218 (b) ("shall have, at all times, access to all orders, prescriptions, and records ***kept or maintained under this chapter, as provided herein***.") (emphasis added). Third, a covered entity may deny access to such records if the entity believes that such disclosure is prohibited by HIPAA. Fourth, authorized law enforcement and state's attorneys have elected not to use 4218 to its fullest extent as a matter of general practice. Fifth, authorized law enforcement and the state's attorneys are subject to the oversight and watchful eyes of the public, the governing bodies of this state, and policies and rules that guide them professionally.

DPS has relied on section 4218 as a successful and necessary tool for protecting the public from the dangers of illegal drug fraud, diversion and abuse for many years without any complaints. DPS does not think any changes to section 4218 are necessary at this time. However, if the committees decide to examine this matter further, DPS may agree to language that limits the access authorized by section 4218 to diversion officers who have received special training as determined necessary and appropriate by the DPS commissioner.

SAS supports the positions and arguments of VDH and DPS.

Appendix I

Title 18: Health

Chapter 84: POSSESSION AND CONTROL OF REGULATED DRUGS

PART V

Foods and Drugs

CHAPTER 84. POSSESSION AND CONTROL OF REGULATED DRUGS

Subchapter I. Regulated Drugs

§ 4218. Enforcement

(a) It is hereby made the duty of the department of public safety, its officers, agents, inspectors, and representatives, and pursuant to its specific authorization any other peace officer within the state, and of all state's attorneys, to enforce all provisions of this chapter and of the rules and regulations of the board of health adopted under this chapter, except those otherwise specifically delegated, and to cooperate with all agencies charged with the enforcement of the federal drug laws, this chapter, and the laws of other states relating to regulated drugs.

(b) Such authorities and their specifically authorized agents shall have, at all times, access to all orders, prescriptions, and records kept or maintained under this chapter, as provided herein.

(c) A person who gives information to law enforcement officers, the drug rehabilitation commission, or professional boards as defined in section 4201 of this title and their specifically authorized agents, concerning the use of regulated drugs or the misuse by other persons of regulated drugs, shall not be subject to any civil, criminal, or administrative liability or penalty for giving such information.

(d) Nothing in this section shall authorize the department of public safety and other authorities described in subsection (a) of this section to have access to VPMS (Vermont prescription monitoring system) created pursuant to chapter 84A of this title, except as provided in that chapter. (1967, No. 343 (Adj. Sess.), § 18, eff. March 23, 1968; amended 1969, No. 203 (Adj. Sess.), § 2; 1991, No. 167 (Adj. Sess.), § 64; 2005, No. 205 (Adj. Sess.), § 2.)