No. _____

In The
Supreme Court of the United States

ALFRED J. GOBEILLE, IN HIS OFFICIAL CAPACITY AS CHAIR OF THE VERMONT GREEN MOUNTAIN CARE BOARD,

Petitioner,

v.

LIBERTY MUTUAL INSURANCE COMPANY,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Vermont, like many other States, requires health care providers and health care payers to provide claims data and related information to the State's health care database. The law applies to all public and private entities that pay for health care services, including insurers, government programs, and third-party administrators. The State relies on the database to inform health care policy. The question presented is:

Did the Second Circuit – in a 2-1 panel decision that disregarded the considered opinion advanced by the United States as amicus – err in holding that ERISA preempts Vermont's health care database law as applied to the third-party administrator for a self-funded ERISA plan?

PARTIES TO THE PROCEEDING

Petitioner Alfred J. Gobeille, in his official capacity as Chair of the Green Mountain Care Board, has been substituted for Commissioner Susan L. Donegan, who was the appellee in the court of appeals. *See* Supreme Court R. 35.3. Chair Gobeille has been substituted because the Vermont Legislature shifted responsibility for the unified health care database to the Green Mountain Care Board, effective June 7, 2013. 2013 Vt. Acts & Resolves, No. 79, § 40. The original defendant in the district court was Commissioner Stephen W. Kimbell. Commissioner Donegan was substituted as a party when she replaced Commissioner Kimbell in office.

The respondent, Liberty Mutual Insurance Company, was the appellant in the court of appeals and the plaintiff in the district court.

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Alfred J. Gobeille, as Chair of the Vermont Green Mountain Care Board, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit in this case.

INTRODUCTION

Health care policy is a pressing concern at every level of government. Many States, including Vermont, rely on health care databases for accurate, complete information to support, inform, and test health care policies. The Second Circuit's unjustified expansion of ERISA preemption in this case threatens these important tools adopted by sixteen States. And the panel majority's reasoning – that state recordkeeping or information-gathering requirements of any kind intrude on core ERISA concerns – applies far more broadly, creating uncertainty about a wide range of health and safety regulations.

In our federal system, the "regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985). This Court cautioned nearly twenty years ago that ERISA was not intended to displace the States' authority over "general health care regulation." *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 661 (1995). The Second Circuit disregarded this Court's direction. It

adopted an expansive view of ERISA preemption that conflicts with this Court's holdings and substantially undermines the States' historic police powers. The States' interests in pursuing their chosen policies, and the harm to those interests caused by the lower court's ruling, strongly support immediate review by this Court.

OPINIONS BELOW

The opinion of the court of appeals (App. 1-47) is reported at 746 F.3d 497. The memorandum opinion and order of the district court (App. 48-80) is not reported, but is available at 2012 WL 5471225.

JURISDICTION

The judgment of the court of appeals was entered on February 4, 2014. Petitioner filed a timely petition for rehearing en banc on February 18, 2014. The petition for rehearing was denied on May 16, 2014. App. 81-82. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Supremacy Clause of the U.S. Constitution provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

U.S. Const. art. VI, cl. 2.

The "other laws" provision of the Employee Retirement Income Security Act (ERISA), 29 U.S.C. § 1144, is set forth at App. 83-90.

Vermont's health care database statute, Vt. Stat. Ann. tit. 18, § 9410, is set forth at App. 92-99. The Appendix also includes the prior version of the statute, before a 2013 amendment that shifted responsibility for the database to the Green Mountain Care Board. App. 99-106.

The Regulation that governs the database, Regulation H-2008-01, is set forth at App. 107-41. The appendices to the Regulation (which include charts, tables, and forms) are available online at http://gmcboard.vermont.gov/sites/gmcboard/files/REG_H-2008-01.pdf.

STATEMENT

1. Vermont's "unified health care database" collects critical information that informs the State's health care policy, including its policy "to ensure that all residents have access to quality health services at costs that are affordable." Vt. Stat. Ann. tit. 18, § 9401(a) (App. 91); *id.* § 9410(a)(1) (App. 92). The database contains information supplied by health care providers and health care "payers" – that is, government agencies, insurers, and similar entities that pay for health care services. *Id*. § 9410(c), (h), (j) (App. 94-99). The purposes of the database include:

> (A) Determining the capacity and distribution of existing resources.
>
> (B) Identifying health care needs and informing health care policy.
>
> (C) Evaluating the effectiveness of intervention programs on improving patient outcomes.
>
> (D) Comparing costs between various treatment settings and approaches.
>
> (E) Providing information to consumers and purchasers of health care.
>
> (F) Improving the quality and affordability of patient health care and health care coverage.

Id. § 9410(a)(1)(A)-(F) (App. 92).

Vermont's Green Mountain Care Board administers the database, known as VHCURES.[1] The Board was created in 2011 to, among other things, improve the health of Vermont residents; reduce the growth of health care costs while protecting access to health care and quality of care; and simplify health care financing and delivery. Vt. Stat. Ann. tit. 18, § 9372.

The Board has a broad array of regulatory and innovative responsibilities, including administering Vermont's health care expenditure analysis, *id.* § 9375a; approving hospital budgets, *id.* § 9375(7); overseeing payment reform pilot projects, *id.* §§ 9375(1), 9377; approving health insurance rates, *id.* § 9375(6); reviewing applications for certificates of need for new health care projects, *id.* § 9375(b)(8); and evaluating the quality of Vermont's health care system, *id.* § 9375(10).

The Board maintains and uses the health care database to "carry out [its] duties." *Id.* § 9410 (App. 92). For example, it uses the data to inform its review of health insurance rates and hospital budgets. Vt. Stat. Ann. tit. 8, § 4062; Vt. Stat. Ann. tit. 18, §§ 9375(b)(6)-(7), 9456. The Board also relies on the data for oversight and evaluation of health care

[1] The Vermont Legislature shifted responsibility for the database from the Department of Financial Regulation to the Green Mountain Care Board during the litigation. 2013 Vt. Acts & Resolves, No. 79, § 40.

payment and delivery system reforms. *Id.* §§ 9375(b)(1), 9377.

The database statute requires "[h]ealth insurers, health care providers, health care facilities, and governmental agencies" to "file reports, data, schedules, statistics, or other information determined by the Board to be necessary to carry out the purposes" of the law. *Id.* § 9410(c) (App. 94). For this purpose, "health insurer" includes "any third party administrator, any pharmacy benefit manager, any entity conducting administrative services for business, and any other similar entity with claims data, eligibility data, provider files, and other information relating to health care provided to Vermont resident[s]." *Id.* § 9410(j)(1)(B) (App. 98). The implementing rule notes that the term "may also include, to the extent permitted under federal law, any administrator of an insured, self-insured, or publicly funded health care benefit plan offered by public and private entities." Regulation H-2008-01, § 3(X) (App. 112-13). Only insurers with 200 or more covered members living in Vermont (or receiving covered services in Vermont) must provide information to the database. *Id.* § 3(Ab) (App. 113).

State Regulation H-2008-01 (App. 107-41) supplies the details of database administration.[2] The rule

[2] Reg. H-2008-01, reprinted at App. 107-41, was promulgated by the Vermont Department of Financial Regulation, which previously administered the database. The regulation remains in effect.

sets forth "requirements for the submission of health care claims data, member eligibility data, and other information relating to health care provided to Vermont residents or by Vermont health care providers." *Id.* § 1 (App. 107). The rule also provides "conditions for the use and dissemination of such claims data." *Id.*

Information is collected and maintained so as to protect personal privacy. The statute requires compliance with the federal Health Insurance Portability and Accountability Act (HIPAA), *see* Vt. Stat. Ann. tit. 18, § 9410(h)(2) (App. 96), and mandates that confidential information be "filed in a manner that does not disclose the identity of the protected person." *Id.* § 9410(e) (App. 94-95). And it prohibits public disclosure of "direct personal identifiers," including names, addresses, and Social Security numbers. *Id.* § 9410(h)(3)(D) (App. 97-98). The statute also calls for a confidentiality code and penalizes violation of confidentiality requirements. *Id.* § 9410(f), (g) (App. 95). The regulation provides standards for code and encryption requirements, Reg. H-2008-01, § 5(A)(5) (App. 119-21), and restricts submission of "direct personal identifiers," *id.* § 7(A)(5) (App. 128-29).

As permitted by HIPAA and these confidentiality requirements, the Board may provide access to data "as a resource for insurers, employers, providers, purchasers of health care, and state agencies to continuously review health care utilization, expenditures, and performance in Vermont." Vt. Stat. Ann. tit. 18, § 9410(h)(3)(B) (App. 97). The regulation

carefully delineates data sets that are publicly available, data that may not be disclosed, and data that is available to researchers that agree to protect confidentiality and control access. Reg. H-2008-01, § 8 (App. 130-39).

2. Respondent Liberty Mutual is an insurance company based in Massachusetts. Liberty Mutual provides health care for about 80,000 employees, retirees, and their families through a self-funded plan governed by ERISA. Liberty Mutual is the "named fiduciary" and "plan administrator" for ERISA purposes. App. 7-8, 50.

Liberty Mutual has employees and does business in Vermont. Its plan provides benefits for 137 Vermont residents. App. 7, 50. Because of its small number of Vermont participants, Liberty Mutual itself is not required to provide information for Vermont's database. App. 8, 58. Liberty Mutual, however, contracts with a third-party administrator, Blue Cross Blue Shield of Massachusetts, to administer the plan. App. 8, 50-51. Blue Cross "processes medical claims . . . , receives participants' confidential medical records and generates claims data." App. 50-51. Blue Cross provides or administers benefits for about 7,000 Vermonters, including Liberty Mutual's plan participants, Ct. App. J.A. 288, so Blue Cross is obligated to provide its data to Vermont. App. 8. It provides that information for other self-funded ERISA plans. App. 72-73 n.5.

Vermont's Department of Financial Regulation (previously responsible for the database) subpoenaed Blue Cross in August 2011, seeking claims data and other required information for the database. App. 8-9. Liberty Mutual directed Blue Cross not to report information for its beneficiaries. Blue Cross complied with the subpoena in all other respects, but did not submit data for Vermont participants in Liberty Mutual's plan. App. 9, 56.

3. Liberty Mutual then filed this lawsuit, claiming that ERISA preempts any requirement that its third-party administrator provide information for Vermont's health care database. App. 9, 48, 56. The State moved to dismiss for lack of standing and failure to state a claim; Liberty Mutual moved for summary judgment. App. 9, 49. With the agreement of the parties, the district court treated the motions as cross-motions for summary judgment. *Id.* In a written decision, the district court rejected Liberty Mutual's preemption claim and granted judgment to the State. App. 48-80.

The district court first held that Liberty Mutual had standing. App. 61. Although Liberty Mutual had no independent obligation to provide information to the database, the regulation required Blue Cross to provide information for Liberty Mutual's plan. App. 58. The court reasoned that Liberty Mutual was "subject to regulation" through the State's regulation of Blue Cross, the third-party administrator. App. 59.

Turning to Liberty Mutual's claim of preemption, the district court noted that a "statute that operates in the health care field will receive the benefit of the presumption against preemption, even if it does not directly regulate health care providers or services." App. 65. The court then held that Liberty Mutual did not "overcome the presumption against preemption." App. 64-66, 79.

First, the court held that the database statute does not have a "reference" to ERISA plans. App. 69. "Vermont's statute and regulation do not act immediately and exclusively upon ERISA plans, nor is the existence of ERISA plans essential to their operation." App. 69. As the court explained, the law requires numerous entities, including insurers and providers, to supply information to the database. *Id.*

Second, the court concluded that the database statute does not have an impermissible "connection with" an ERISA plan. App. 70-78. After surveying this Court's decisions and relevant circuit precedent, the district court emphasized that Vermont's law: (1) did not "attempt to control, supersede or interfere with the operation of an ERISA plan"; (2) "has no effect whatsoever on the core relationships that ERISA was designed to protect – those between participants, beneficiaries, administrators and employers"; and (3) has "no effect whatsoever on the core ERISA functions – such as processing claims or disbursing benefits." App. 79.

The court recognized that even a generally applicable law might be preempted if it "creates an economic effect so acute as to dictate certain administrative choices." App. 72. Here, however, Liberty Mutual had no reporting obligations at all, and there was "no evidence" that its third-party administrator, Blue Cross, was "laboring under any sort of burden" in complying with the law. App. 72 n.5. Blue Cross provided the information for other ERISA plans. App. 73 n.5. Liberty Mutual did "not submit[ ] any information about any actual burden suffered by itself or [Blue Cross] in producing this information." *Id.*

4. On appeal, the Second Circuit reversed in a split decision. App. 1-47. While agreeing with the district court that Vermont's statute and regulation "lack 'reference to' an ERISA plan," App. 23 n.9, the majority held that Vermont's law has an impermissible "connection with" ERISA plans. App. 23. In a footnote, the majority concluded that Vermont's health care database law was not an exercise of "the states' historic police powers" and declined to apply the presumption against preemption. App. 18 n.8.

The court viewed "reporting" as a core ERISA concern that is undermined by any state requirement for "plan record-keeping, and filing with a third party." App. 23-24. It emphasized that Vermont's database "is called the 'Vermont Healthcare Claims Uniform *Reporting* and Evaluation System.' " App. 24. The majority viewed as irrelevant the fact that

Vermont's database seeks information unrelated to ERISA's reporting requirements. App. 24 n.11.

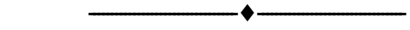
The court concluded that, consistent with ERISA, only a "slight reporting burden" would be permissible. App. 24. The majority saw Vermont's "scheme" as "obviously intolerable," describing the claims data reporting requirements as "burdensome, time-consuming, and risky." App. 25. Other than merely citing the regulation, however, the court pointed to no evidence of financial costs or other burdens. The court further reasoned that any "burdens and risks must be multiplied" because of unspecified reporting requirements in other states. App. 29. The court described Vermont's detailed confidentiality provisions as "complex but loose" and suggested that the regulation was problematic because it could be changed in the future. App. 27-28.

Based on this reasoning, the majority held Vermont's law preempted. App. 23-29. It reached this conclusion without addressing the United States Department of Labor's support, as amicus curiae, for the district court's decision and Vermont's position.

Judge Straub dissented. App. 30-47. The dissent sharply criticized the majority for failing to apply the presumption against preemption. App. 33-34. Judge Straub also pointed out that the majority's description of Vermont's reporting requirement as "time-consuming and risky" was "pure speculation." App. 46. "There is no evidence to support such a finding." *Id.*

The dissent reasoned that Vermont's health care database is "wholly distinct" from ERISA's reporting requirements and seeks "after-the-fact information which plan administrators . . . already have in their possession." App. 38, 39. "The Vermont statute regulates health care within that state, while imposing a purely clerical burden on ERISA plans." App. 46. The law "does not hinder the national administration of employment benefit plans" or require any "distinction in benefits between Vermont and any other state." App. 44. For the dissent, that "end[ed] the inquiry." *Id.*

5. Vermont filed a timely petition for rehearing en banc, which was denied on May 16, 2014. App. 81-82.



REASONS FOR GRANTING THE WRIT

This Court should grant review to address the Second Circuit's broad and unprecedented expansion of ERISA preemption. The lower court's decision sharply conflicts with this Court's ERISA jurisprudence. It will have a profound impact on health care regulation in sixteen States with programs like the one held preempted here. And because the Second Circuit has introduced uncertainty into an important area of the law, its decision, if left in place, will have a substantial impact on state and federal regulatory interests.

1. The lower court's ruling is not merely an erroneous application of the law. The Second Circuit embraced an expansive view of ERISA preemption that this Court – after many years and countless ERISA cases – firmly rejected in *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co*, 514 U.S. 645, 654-56 (1995). Vermont's database statute is a generally applicable law through which the State obtains information from the health care industry to develop policies that support the health and well-being of its citizens. It is not targeted at ERISA plans. It does not regulate the benefits provided, plan governance or finances, or the relationship between the plan and its participants. It is therefore not preempted by ERISA. The Second Circuit held otherwise only by disregarding settled principles – including the scope of the States' historic police powers and the presumption against preemption. The unacceptable and irreconcilable conflict with this Court's precedents warrants immediate review, a conclusion supported by a recent Sixth Circuit decision "disagree[ing]" with the Second Circuit's "literal approach to [ERISA] preemption," *see Self-Ins. Inst. of America, Inc. v. Snyder*, No. 12-2264, 2014 WL 3804355, at *7 (6th Cir. Aug. 4, 2014) [hereinafter "*SIIA*"].

2. The importance of the issue presented further justifies granting the petition. The decision below undermines efforts by at least sixteen States – including all three States in the Second Circuit – to create and use comprehensive health care databases.

The breadth of the lower court's decision also casts a shadow over a wide range of other state regulations. In contrast to this Court's holdings, which recognize that States may permissibly impose administrative costs and burdens on ERISA plans, the Second Circuit has deemed routine recordkeeping and submission of information to be a "core" ERISA concern. App. 23-24. The decision thus provides a basis for challenging state health care regulations, taxes, licensing, and safety rules – all of which typically require recordkeeping and reporting of compliance information.

The lower court's ruling treads on both state and *federal* interests. The United States Department of Labor voluntarily participated as amicus curiae in the court of appeals and supported the district court's decision and Vermont's position. Despite the Department's recognized expertise in ERISA – and its administration of ERISA's reporting requirements – the 2-1 panel decision of the Second Circuit rejected (without any discussion whatsoever) the Department's considered position. The Department's decision to participate as an amicus confirms that this case – and the scope of ERISA preemption generally – is a matter of pressing importance to the federal government as well as the States.

I. The decision below is an unprecedented expansion of ERISA preemption that conflicts with this Court's decisions in *Travelers*, *Dillingham*, and *De Buono*.

This Court has repeatedly disavowed the "expansive and literal" approach to ERISA preemption that the 2-1 panel decision of the Second Circuit adopted in this case. *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 812-14 (1997); *see also Travelers*, 514 U.S. at 654-56. Instead, this Court's decisions establish a framework for evaluating claims of ERISA preemption that focuses on the purposes of ERISA and acknowledges the States' primary role in regulating matters of health and safety. The Second Circuit's decision marks a clear and unacceptable conflict with this Court's precedent.

A. *Travelers* and *De Buono* narrowed ERISA preemption by focusing on Congress's intent and reaffirming the presumption that Congress does not intend to displace state law in areas traditionally regulated by the States.

This Court's decisions in *Travelers* and *De Buono* narrowed and focused the scope of ERISA preemption in three important ways. First, the Court rejected an approach to preemption grounded in "uncritical literalism," instead directing courts to look to "the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive." *Travelers*, 514 U.S. at 656. Given the

"frustrating difficulty" of interpreting ERISA's "unhelpful text," *Travelers* and *De Buono* hold that the preemption inquiry must be guided by ERISA's underlying objectives and purposes. *Id.*; *De Buono*, 520 U.S. at 813.

Second, *Travelers* delineated the key areas in which ERISA preempts state law. The "basic thrust of the preemption clause . . . was to avoid a multiplicity of regulation in order to permit the nationally uniform administration of employee benefit plans." *Travelers*, 514 U.S. at 657. Accordingly, ERISA "preempt[s] state laws that mandate[ ] employee benefit structures or their administration." *Id*. at 658. Preempted state laws include coverage mandates, anti-subrogation rules, alternative enforcement mechanisms, and laws affecting benefit calculations. *Id*. at 657-58. Later cases reiterated this core concern with state laws that "require[ ] employers to provide certain benefits" or govern the calculation of benefits. *De Buono*, 520 U.S. at 815; *see also Cal. Div. Labor Standards Enforcement v. Dillingham Constr.*, 519 U.S. 316, 328 (1997).

Third, the Court "unequivocally concluded" that ERISA's preemption clause does not modify the presumption against preemption of state law. *De Buono*, 520 U.S. at 813. The Court explained in *Travelers* that it "never assume[s] lightly that Congress has derogated state regulation." 514 U.S. at 654; *see also Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (describing the presumption against preemption as a "cornerstone" of the Court's preemption jurisprudence). Nothing in

ERISA "indicates that Congress chose to displace general health care regulation, which historically has been a matter of local concern." *Travelers,* 514 U.S. at 661. ERISA accordingly does not preempt "'myriad state laws' of general applicability that impose some burdens on the administration of ERISA plans." *De Buono*, 520 U.S. at 815 (quoting *Travelers*, 514 U.S. at 668); *see also Dillingham*, 519 U.S. at 333-34.

These principles have provided direction to the States and to the lower courts for almost 20 years. Claims of ERISA preemption "generated an avalanche of litigation" in the years after ERISA's adoption. *De Buono*, 520 U.S. at 808-09 n.1. *De Buono* was the Court's sixteenth ERISA preemption case and the third case just that term. *See id.* The series of decisions in *Travelers*, *De Buono*, and *Dillingham* cabined ERISA preemption to a reasonable scope, and gave state policymakers necessary guidance on the line between federal and state authority. As explained below, the Second Circuit in this case departed so substantially from this controlling precedent that its decision creates an unacceptable degree of confusion and uncertainty.

B. The lower court departed from these settled principles and adopted a broad interpretation of ERISA preemption that directly conflicts with this Court's holdings.

As the United States argued below, Vermont's law is not preempted because it "does not regulate the

structures or core functions of ERISA plans." U.S. Ct. App. Br. 11. The Second Circuit concluded otherwise only by disregarding this Court's teachings about the scope of ERISA preemption.

1. The Second Circuit engaged in precisely the kind of rigid, literal analysis that this Court disavowed in *Travelers* and *De Buono*. The panel majority's decision was predicated on its view that, because ERISA governs plan reporting, any type of state reporting requirement must intrude on a core ERISA concern. Consistent with that literal approach, the court emphasized that Vermont's law requires Liberty Mutual's third-party administrator to "*report*" claims data for the health care database. App. 23-24. But Vermont's law does not intrude on an area of core ERISA concern merely because it seeks information from the plan administrator. This Court explained in *Dillingham* that "[i]n enacting ERISA, Congress' primary concern was with the mismanagement of funds accumulated to finance employee benefits and the failure to pay employees benefits from accumulated funds." 519 U.S. at 326-27 (quotation omitted). It was "*[t]o that end*" that Congress "established extensive reporting, disclosure, and fiduciary duty requirements to insure against the possibility that the employee's expectation of the benefit would be defeated through poor management by the plan administrator." *Id.* (emphasis added) (quotation omitted). The Second Circuit's myopic focus on the word "reporting," instead of the purposes of ERISA, conflicts with *Travelers* and *Dillingham*. Recognizing

these principles established by this Court's precedents, the Sixth Circuit in *SIIA* "disagree[d]" with the Second Circuit's "literal approach to preemption," *SIIA*, 2014 WL 3804355, at *7. The *SIIA* court, in line with this Court's rulings, acknowledged ERISA's principal concern with the financial solvency of plans, and held that Congress did not intend ERISA's reporting requirements to "preclude states from enacting laws imposing administrative burdens – of any kind – upon plan administrators and sponsors unrelated to the administration of the plans." *Id*. at *5.

Vermont's health care database – as the United States observed in its filing below – is unrelated to ERISA's core concern with plan administrators' fiduciary responsibilities to beneficiaries. "The focus and purpose of Vermont's data collection . . . are quite different" from ERISA's concerns. U.S. Ct. App. Br. 12. Vermont seeks claims data to improve health care quality, affordability, and effectiveness, Vt. Stat. Ann. tit. 18, § 9410(a) (App. 92), and seeks no information whatsoever about plan funding or governance. By contrast, a plan's annual report to the Secretary of Labor is "principally concerned with the financial soundness of the plan." U.S. Ct. App. Br. 12. The Vermont law does not protect beneficiaries or provide them with information; indeed, the law "does not include disclosure requirements affecting the employer-employee or plan-participant relationship." U.S. Ct. App. Br. 13. Given the sharp disconnect between ERISA's objectives and the purposes of Vermont's law, the dissent below aptly observed that the

"majority's argument misses the nuance of what 'reporting' means in the context of ERISA, and ignores the case law's focus on whether the *administration of benefits to beneficiaries* is impacted." App. 32 (Straub, J., dissenting); *see also SIIA*, 2014 WL 3804355, at *7 (quoting same).

2. The lower court's analysis also contravenes this Court's guidance about the types of state laws preempted by ERISA. Together, *Travelers*, *Dillingham,* and *De Buono* teach that ERISA's central concern is with state laws that dictate the types of benefits provided by plans or the manner in which plans administer those benefits. *Travelers,* 514 U.S. at 657-58; *Dillingham*, 519 U.S. at 328, 333-34; *De Buono*, 520 U.S. at 815. Vermont's health care database does not touch on these areas. The law "does not meaningfully regulate plans' benefit programs or affect plans' administration of benefits." U.S. Ct. App. Br. 14-15.

Instead of recognizing these limits on the scope of ERISA preemption, the Second Circuit panel majority mistakenly focused on the law's supposed administrative burdens. But ERISA does not preempt "'myriad state laws' of general applicability that impose some burdens on the administration of ERISA plans." *De Buono*, 520 U.S. at 815 (quoting *Travelers*, 514 U.S. at 668). Administrative cost or burden is relevant only if the burden is "so acute 'as to force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers.'" *De Buono*, 520 U.S. at 816 n.16 (quoting *Travelers*, 514 U.S. at

668). As the dissenting opinion concluded, there was "no basis to find that the Vermont statute would cause Liberty Mutual to increase its costs more than a *de minimus* amount . . . much less . . . cause a fiduciary to change a plan in any way." App. 40-41 (Straub, J., dissenting).[3]

In short, the lower court's decision irreconcilably conflicts with both the reasoning and the results reached in this Court's precedents. The Court has

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[3] The majority's description of the supposed burdens is factually unsupported and wrong. As the district court pointed out, Liberty Mutual submitted no evidence of "any actual burden." App. 72-73 n.5. On appeal, Liberty Mutual merely asserted that "all regulations have their costs" and claimed that Vermont's law was "*per se* burdensome." Liberty Mutual Ct. App. Br. 28. The dissent highlighted Liberty Mutual's failure "to provide any details or showing of the alleged burden," and sharply criticized the majority for engaging in "pure speculation" on this point. App. 39, 46 (Straub, J., dissenting). As the dissent noted, Vermont's law "asks for after-the-fact information which plan administrators . . . already have" and "by all accounts [Blue Cross] is happy to provide the data . . . and . . . does so for other clients." App. 39 (Straub, J., dissenting). Moreover, while this case was pending on appeal, the federal Centers for Medicare and Medicaid Services (CMS) agreed to provide its claims data to Vermont's database. *See* Data Use Agreement Between CMS and Green Mountain Care Board (No. 25534), *available at* http://gmcboard.vermont.gov/sites/gmcboard/files/CMS_DUA_%2025534_SIGNED_Attachment_A_ExSum.pdf. That agreement confirms the federal government's confidence in Vermont's program, and undercuts any suggestion that the database provides inadequate confidentiality protections. Protecting personal privacy is critical to this program. There was "no evidence" to support a contrary conclusion. App. 46 (Straub, J., dissenting).

repeatedly upheld state laws that challengers described as imposing costs and burdens on ERISA plans. In *Mackey v. Lanier Collection Agency*, 486 U.S. 825, 831 (1988), the plan administrators complained of "substantial administrative burdens and costs" caused by state-law garnishment proceedings. The Court rejected the preemption claim. *Id.* at 832, 841. In *Dillingham*, the Court upheld a California law regulating apprenticeship programs, even though the law required a plan to either obtain state approval for its program or pay a higher minimum wage to apprentices. 519 U.S. at 319-21, 330-33.

And most relevant here, in *De Buono* the Court held that New York could permissibly tax the gross receipts of a hospital operated by an ERISA plan. 520 U.S. at 814-16. The generally applicable tax was not preempted even though it "increase[d] the cost of providing benefits" and had "some effect" on plan administration. *Id.* at 816. Taxation inevitably requires "particular form[s] of record-keeping"; likewise, taxes are potentially "inconsistent" from state to state. *See* App. 22-23. As the Sixth Circuit noted in *SIIA,* although "neither *Travelers* nor *De Buono* explicitly concerned reporting requirements regarding the taxes . . . those requirements were essential parts of the tax schemes and drew no comment." *SIIA*, 2014 WL 3804355, at *6. Moreover, the tax upheld in *De Buono* directly depleted plan assets.

Given this controlling precedent, the Second Circuit erred in holding that ERISA tolerates, at most, only a "slight reporting burden" on plans. App.

24. State laws of all kinds, from employment, licensing, and taxes to health and safety regulations, require "record-keeping, and filing with a third party." App. 24. It cannot be that ERISA preempts generally applicable state laws, unrelated to the objectives of ERISA, merely because those laws involve data collection or record-keeping.

3. The Second Circuit's refusal to apply the presumption against preemption also "flies in the face of clear Supreme Court precedent." App. 33 (Straub, J., dissenting). In a footnote, the court held that Vermont's law is not an exercise of the "states' historic police powers." App. 18 n.8. "[C]ollecting data," the majority opined, is not "historic" and "health data collection laws do not regulate the safe and effective provision of health care services." *Id.* This squarely conflicts with *De Buono*. *De Buono* held that New York's tax "clearly operates in a field that has been traditionally occupied by the States." 520 U.S. at 814 (quotation omitted). That was true even though the tax, first adopted in 1990, was a "revenue raising measure, rather than a regulation of hospitals." *Id.* at 809, 814; *see also id.* at 814 n.10 (fact that tax targets health care industry supports application of the presumption).[4]

[4] The footnote concluded that "[i]n any event, the Supreme Court has repeatedly found the presumption overcome if the state laws 'upset the deliberate balance central to ERISA,' even if those laws 'implement policies and values lying within the traditional domain of the States.' " App. 18-19 n.8 (quoting *Boggs*

(Continued on following page)

Given the "considerable burden of overcoming" the presumption, *De Buono*, 520 U.S. at 814, Liberty Mutual's failure to prove any cost or administrative burden should have ended the inquiry. *See* App. 72-73 n.5 (district court); App. 39-41, 44 (Straub, J., dissenting). Yet the lower court assumed that Vermont's law was "burdensome" and "obviously intolerable." App. 25. Its judgment rested on speculation not just about Vermont's statute but about other states' laws and ways in which Vermont could change its program in the future. App. 25, 27-29. Consistent with this Court's precedents, the Second Circuit should have presumed the statute's constitutionality, not the opposite.

II. The Second Circuit's unduly broad preemption holding treads on state and federal interests and is an important issue worthy of this Court's immediate review.

The Second Circuit did not merely err in its application of precedent. The lower court returned to an expansive view of ERISA preemption that this Court has disavowed. Its flawed analysis of burden and cramped view of the states' historic police powers

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v. Boggs, 520 U.S. 833, 840, 854 (1997)). Nowhere in its analysis, however, does the majority apply the presumption against preemption or explain that the presumption is overcome. The lower court's holding, as the dissenting opinion recognizes, is that the presumption does not apply. App. 33 (Straub, J., dissenting).

will sow confusion and uncertainty. That is especially troubling in this context because, read literally, ERISA's preemption language suggests "a degree of pre-emption that no sensible person could have intended." *Dillingham*, 519 U.S. at 335-36 (Scalia, J., concurring). This Court should grant review to correct the Second Circuit's broad and unjustified expansion of ERISA preemption. And, as explained below, further review should be immediate because the Second Circuit's holding poses a serious threat to important state and federal interests.

A. The lower court's unwarranted expansion of ERISA preemption is a matter of exceptional importance to state legislators and regulators.

The Second Circuit's ruling threatens to undermine efforts by at least sixteen States to create and use databases similar to Vermont's. The breadth of the lower court's decision also casts a shadow over other state regulatory efforts in a field – health care – that is traditionally and primarily the responsibility of the States.

1. The Second Circuit's decision in this case undermines a widespread and crucial tool that States use to inform health care policy. At least ten other States have similar programs, known as all-payer

claims databases, already in place.[5] Five other States are creating databases,[6] and many more are considering doing so. Jo Porter et al., APCD Council, *The Basics of All-Payer Claims Databases* 1 (January 2014).[7] Claims databases are increasingly popular because states need "robust information about the costs and performance of their state's health care delivery system." Patrick B. Miller et al, State Coverage Initiatives, *All-Payer Claims Databases: An Overview for Policymakers* 2 (May 2010).[8] These databases "fill critical information gaps" and allow states "to understand the cost, quality, and utilization of health care for their citizens." *Id.*; Porter, *supra*, at 1. By collecting accurate, complete information about the provision of health care services, States are bringing transparency to the health care market, collecting

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[5] *Colorado*: Col. Rev. Stat. § 25.5-1-204; *Kansas*: Kan. Stat. Ann. § 65-6804; *Maine*: Me. Rev. Stat. Ann. tit. 22, §§ 8703, 8704; *Maryland*: Md. Code Ann., Health-Gen. § 19-133; *Massachusetts*: Mass. Gen. Laws Ann. ch. 12C, § 12; *Minnesota*: Minn. Stat. Ann. § 62J.321; *New Hampshire*: N.H. Rev. Stat. Ann. § 420-G:11-a; *Oregon*: Or. Rev. Stat. § 442.466; *Tennessee*: Tenn. Code Ann. § 56-2-125; *Utah*: Utah Code Ann. § 26-33a-106.1.

[6] *Connecticut*: Conn. Gen. Stat. § 38a-1091; *New York*: N.Y. Pub. Health § 2816; *Rhode Island*: R.I. Gen. Laws § 23-17.17-10; *Virginia*: Va. Code Ann. § 32.1-276.7:1; *West Virginia*: W. Va. Code § 33-4A-2.

[7] Available at: http://www.apcdcouncil.org/sites/apcdcouncil.org/files/The%20Basics%20of%20All-Payer%20Claims%20Databases.pdf.

[8] Available at: http://www.statecoverage.org/files/SCI_All_Payer_Claims_ReportREV.pdf.

critical cost information, and improving the quality of care.

Cost. It is impossible to overestimate the States' need for accurate and complete information about health care spending. The "projected growth in health-related costs" is the "primary driver of fiscal challenges for the state and local government sector in the long term." U.S. Government Accountability Office, *State and Local Governments' Fiscal Outlook* 5 (April 2012 Update).[9] Knowledge gaps "limit the ability to identify opportunities to address rising health care costs." Miller, *supra*, at 2. A true all-payers claims database provides this critical data. States may use this information to inform budgeting, rate-setting, and other policy decisions, and to measure the impact of reforms and pilot projects. *See, e.g.,* Chris Kardish, *More States Create All-Payer Claims Databases*, Governing (Feb. 4, 2014);[10] Miller, *supra*, at 2, 5; Porter, *supra*, at 2.

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[9] Available at: http://www.gao.gov/assets/590/589908.pdf. National spending on health care reached $2.79 trillion in 2012, more than double the level in 2000. Office of the Actuary, Centers for Medicare & Medicaid Services, *National Health Expenditures Tables*, Table 1, *available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/tables.pdf.

[10] Available at: http://www.governing.com/topics/health-human-services/gov-states-serious-about-health-data.html.

Transparency. State health care databases are bringing transparency to the health care marketplace. Lack of information about cost and quality is a serious problem for consumers, who "generally learn of their health care costs after receiving care, such as when they receive a bill." U.S. Government Accountability Office, *Health Care Price Transparency* 2 (September 2011).[11] Now, with a few keystrokes, consumers in some states have access to information that used to be burdensome or even impossible to find. Both Maine and New Hampshire, for example, have websites that allow consumers to compare costs across providers.[12] Other States are planning similar sites. *See* Christine Vestal, *Can Claims Data Crack the Health Care Cost Riddle?* USA Today (June 17, 2014) (discussing Utah and Colorado).[13]

Quality of Care. An all-payer claims database is a powerful public health tool. Policymakers can evaluate access to necessary services. Researchers can track chronic disease indicators, evaluate whether clinical care guidelines are met, and study specific problems such as adverse drug reactions and emergency room visits. Miller, *supra*, at 6-8. The data allow States not just to pinpoint problems but to

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[11] Available at: http://www.gao.gov/assets/590/585400.pdf.

[12] *See* Maine HealthCost, https://mhdo.maine.gov/healthcost 2014/ (last visited Aug. 3, 2014); New Hampshire HealthCost, http://www.nhhealthcost.org/ (last visited Aug. 3, 2014).

[13] Available at: http://www.usatoday.com/story/news/nation/2014/06/17/stateline-health-care-claims-data/10665577/.

assess whether proposed solutions are working. This "rich and deep source of health care data"[14] is a critical resource that States use to protect and improve the health and welfare of their citizens.

The Second Circuit's decision threatens these innovative programs. Self-insured ERISA plans, like Liberty Mutual's plan, provide coverage to millions of Americans. Nationally, over 60% of workers who receive health coverage through employment are in a self-funded plan. *See* Kaiser Family Foundation, *Employer Health Benefits 2013 Annual Survey*, at 176.[15] As the United States explained below, exempting self-insured plans from the database "would leave a large hole in the data collection the state has fashioned to further its state healthcare policies" and "seriously stymie Vermont's efforts to improve medical outcomes for its residents." U.S. Ct. App. Br. 10. Nothing in ERISA suggests that Congress wanted to create this kind of information vacuum.

This important question of ERISA preemption – relevant to at least sixteen States – is worthy of this Court's immediate review. The decision below does not address a new or emerging legal issue that needs further consideration in the lower courts. Rather, the

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[14] Utah All Payer Claims Database: Description and Background, http://health.utah.gov/hda/apd/about.php (last visited Aug. 3, 2014).

[15] Available at: http://kff.org/private-insurance/report/2013-employer-health-benefits/.

Second Circuit disregarded established precedent and returned to an expansive view of ERISA preemption that unacceptably limits state authority. Its decision governs not just Vermont's program, but also similar databases under development in New York and Connecticut. And all other States must administer (or establish) their programs under the cloud of that decision. The impact on these programs outweighs any negligible benefit from allowing the issue to develop further in the lower courts. Indeed, if this Court denies review, other states may adhere to the Second Circuit's ruling rather than risk litigation – reducing the likelihood any benefit will be gained from percolation.

2. Review is also warranted because the Second Circuit's broad holding has repercussions beyond these particular programs. As this Court recognized almost two decades ago, nothing in ERISA "indicates that Congress chose to displace general health care regulation, which historically has been a matter of local concern." *Travelers*, 514 U.S. at 661. Yet the Second Circuit essentially held that any state record-keeping or information-gathering requirement intrudes on a "core" ERISA concern. App. 23-24. Many ordinary state health-care regulations and other health and safety standards require record-keeping and reporting of information. The Sixth Circuit correctly recognized, in *SIIA,* that such a broad view of ERISA preemption of state reporting requirements as extending to "paperwork" and record preservation is unworkable, and that "ERISA does not reach so

far." *SIIA*, 2014 WL 3804355, at *6. The Second Circuit's reasoning in this case creates uncertainty across a wide swath of traditional state regulation.

Regulation of hospitals and other health care services. As addressed in *De Buono*, ERISA plans may operate their own hospitals and health care centers. The provision of health care services is closely regulated by state law and routinely requires recordkeeping and reporting to state regulators. For example, States commonly require hospitals to provide frequent reports on finances, patient census, staffing levels and other quality and safety measures.[16] Under the Second Circuit's reasoning, these frequent reports would be preempted unless the State shows that the burdens imposed are "slight." App. 24.

Taxation. This Court held in *De Buono* that an ERISA plan must pay a generally applicable state tax on gross hospital receipts. 520 U.S. at 816. Courts have rejected preemption challenges to other state taxes, including a tax on covered health care claims. In *SIIA*, the Sixth Circuit rejected an ERISA preemption challenge to Michigan's tax on paid health care

[16] *See, e.g.,* Conn. Gen. Stat. § 19a-654 (data submission); *id.* §§ 19a-644, 19a-649, § 19a-676 (hospital reports); 210 Ill. Comp. Stat. 85/25 (Hospital Report Card Act); N.Y. Comp. Codes R. & Regs, tit. 10, § 440.1 *et seq.* (hospital annual reports); Tex. Code Ann. § 257.005 (hospital staffing reports); *id.* § 311.033 (financial and utilization data); Vt. Stat. Ann. tit. 18, §§ 1854, 9405b (hospital reports).

claims, because the state law did not alter which benefits were offered, how they were calculated, or to whom they were disbursed, and thus did not interfere with plan administration. *SIIA*, 2014 WL 3804355, at *3-4. The court also held that the state law reporting and recordkeeping requirements at issue did not create improper administrative burdens for ERISA plans and thus did not conflict with ERISA's reporting obligations. *Id.* at *4-7.[17] *See also Boyle v. Anderson*, 68 F.3d 1093 (8th Cir. 1995) (rejecting ERISA preemption challenge to provider tax); *Thiokol Corp. v. Roberts*, 76 F.3d 751 (6th Cir. 1996) (rejecting ERISA challenge to state business tax). Taxes necessarily involve frequent and state-specific recordkeeping and reporting requirements – the same type of requirements that the Second Circuit found unacceptable in this case. The lower court's ruling thus creates uncertainty on an issue that was settled by *De Buono*.

Licensing and safety standards. ERISA plans may employ lawyers, to offer "prepaid legal services," and doctors, to offer medical and surgical care. 29 U.S.C. § 1002(1) (defining employee welfare plan).

[17] The Sixth Circuit's suggestion that the Vermont database law "actually affects the administration of plans," *SIIA*, 2014 WL 3804355, at *7, is unsupported. Further, the Sixth Circuit, like the Second Circuit, offered no support for its conclusion that the creation of a database for the purposes of improving Vermonters' health outcomes and controlling the rate of health care cost growth is not an exercise of traditional state concern, and thus not entitled to the presumption against preemption.

Doctors and lawyers must comply with state licensing requirements, including reporting and recordkeeping requirements for professional education and client trust funds.[18] ERISA plans may operate day care centers, *id.*, which must be licensed and maintain detailed records showing compliance with state regulations.[19] Many ERISA plans run apprenticeship programs, which must satisfy state-law safety standards. *See, e.g., Wright Elec., Inc. v. Minn. State Bd. of Elec.*, 322 F.3d 1025, 1031-32 (8th Cir. 2003) (rejecting ERISA preemption challenge to state regulation mandating supervision of apprentices). The Third Circuit, which recently rejected a preemption challenge to a New Jersey prevailing wage law, noted that the law "require[d] that every contractor and subcontractor keep a record detailing the worker's name, his or her craft or trade, and actual hourly rate of wages paid to each worker." *N.J. Carpenters & Trs.*

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[18] For doctors, *see, e.g.*, N.J. Stat. Ann. § 45:9-7.1; Conn. Gen. Stat. § 20-10b; *see also* Medscape, State CME Requirements, http://www.medscape.org/public/staterequirements (last visited Aug. 3, 2014) (collecting requirements by state). For lawyers, *see, e.g.*, Cal. R. Prof. Conduct, Rule 4-100 (recordkeeping and audit requirements for client trust funds); N.Y. R. Prof. Conduct, Rule 1.15 (similar); Vt. R. Mandatory Continuing Legal Educ., § 9 (reporting requirements for continuing legal education); *see also* American Bar Association, Mandatory CLE, http://www.americanbar.org/cle/mandatory_cle.html (last visited Aug. 3, 2014) (collecting education requirements by state).

[19] *See, e.g.,* Vermont Early Childhood Program Licensing Regulations, § III(C) (Policies, Procedures, Records and Reports), *available at:* http://dcf.vermont.gov/sites/dcf/files/pdf/cdd/care/Early_Childhood_Program.pdf.

v. Tishman Constr. Corp., No. 13-3005, 2014 WL 3702591, at *2, 6 (3d Cir. July 28, 2014) (holding that state-law claim under prevailing wage law was not completely preempted by ERISA). Challenges to any of these state laws could easily be recast as objections to reporting or recordkeeping requirements.

The Sixth Circuit has observed that there is no "state-law-free zone around everything that affects an ERISA plan." *Assoc. Builders & Contractors v. Mich. Dep't of Labor*, 543 F.3d 275, 284 (6th Cir. 2008) (discussing potential consequences of a broad view of ERISA preemption). The Second Circuit's reasoning, however, risks just that result. And even if other courts ultimately narrow or decline to follow the Second Circuit's approach in this case, the lower court's ruling may generate another "avalanche" of ERISA litigation. *Cf. De Buono*, 520 U.S. at 809 n.1. The threat of litigation alone burdens States and influences state policy choices. The decision below thus has serious implications for state legislation and regulation far beyond the context of all-payer databases. It should not be allowed to stand.

B. The U.S. Department of Labor's appearance as an amicus in the court of appeals confirms that the scope of ERISA preemption is a pressing and important issue for the federal government.

The fact that the United States participated in this case as amicus curiae and argued against

preemption confirms the importance of the issue. The United States Department of Labor administers ERISA, including the law's reporting requirements. The Department took the unusual step of appearing as an amicus in the court of appeals to *defend* the decision of the district court. The Department's amicus filing shows that the scope of ERISA preemption is an important issue for the federal government, as well as the States.

The Second Circuit ignored the views of the United States and applied ERISA preemption far more broadly than the Department advocated. The Department, through its Employee Benefit Security Administration, creates and administers reporting requirements for ERISA plans. The Department explained to the court of appeals that Vermont's law does not conflict with ERISA's reporting requirements; that the "focus and purpose of Vermont's data collection" are "quite different" from ERISA's financial reporting and disclosure requirements; and thus the database statute "is like any other 'tenuous, remote or peripheral' law that requires information from businesses or other entities for regulatory purposes." U.S. Ct. App. Br. 12 (quoting *Travelers*, 514 U.S. at 661). Despite the Department's obvious expertise and interest, the panel majority did not even acknowledge the Department's position.

As the Department's amicus participation shows, the decision below adversely affects federal as well as state interests. The federal government has a substantial interest in the division of state and federal

regulatory authority in areas such as health care. Collecting claims data is not something the Department does and is not, in the Department's view, a matter with which ERISA is concerned. The federal government is careful to guard those areas that ERISA shields from state regulation, but it also recognizes the States' traditional authority over "'general health care regulation.'" U.S. Ct. App. Br. 10 (quoting *Travelers*, 514 U.S. at 661). By holding Vermont's law preempted, the Second Circuit has effectively challenged the Department's view of the scope and purpose of ERISA's reporting requirements.

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The decision below broke sharply with this Court's controlling precedents, in a way that harms state interests and creates uncertainty for States and lower courts. Its sweeping expansion of ERISA preemption calls for immediate review.

———♦———

CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,

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August 13, 2014

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

August Term, 2013

(Argued: November 18, 2013 Decided: February 4, 2014)

Docket No. 12-4881-cv

- -x

LIBERTY MUTUAL
INSURANCE COMPANY,

Plaintiff-Appellant,

-v.-

SUSAN L. DONEGAN, IN HER CAPACITY
AS THE COMMISSIONER OF THE VERMONT
DEPARTMENT OF FINANCIAL REGULATION,

Defendant-Appellee.

- -x

Before: KEARSE, JACOBS, and STRAUB, *Circuit Judges.*

Liberty Mutual Insurance Co. appeals from a judgment entered in the United States District Court for the District of Vermont (Sessions, *J.*). The district court concluded that the Employee Retirement Income Security Act of 1974 does not preempt a Vermont statute and regulation requiring self-insured employee health plans to report to the state, in specified format, claims data and "other information relating to health care." For the following reasons, we

reverse and remand with instructions to enter judgment for Liberty Mutual.

Judge STRAUB dissents in part and concurs in part in a separate opinion.

NANCY G. ROSS, McDermott Will & Emery LLP, Chicago, IL (John A. Litwinski, McDermott Will & Emery LLP, Chicago, IL; M. Miller Baker, McDermott Will & Emery LLP, Washington, DC, *on the brief*), *for Appellant*.

BRIDGET C. ASAY, Assistant Attorney General, Office of the Attorney General, Montpelier, VT *for* William H. Sorrell, Attorney General, State of Vermont, *for Appellee*.

KATHRYN COMERFORD TODD, National Chamber Litigation Center, Washington, DC (Jane E. Holman, National Chamber Litigation Center, Washington, DC; Carol Connor Cohen and Nancy S. Heermans, Arent Fox LLP, Washington, DC, *on the brief*), *for amicus curiae Chamber of Commerce of the United States of America in support of Appellant*.

MELISSA MOORE, U.S. Department of Labor, Washington, DC (M. Patricia Smith, Solicitor of Labor; Timothy D. Hauser, Associate Solicitor; Nathaniel I. Spiller, Counsel for Appellate and Special Litigation, *on the*

brief), *for amicus curiae Acting Secretary of the United States Department of Labor in support of Appellee*.

DENNIS JACOBS, *Circuit Judge*:

Liberty Mutual Insurance Co. operates a self-insured employee health plan. A Vermont statute requires all "health insurers" (including self-insured plans) to file with the State reports containing claims data and other "information relating to health care." A State regulation specifies how such information must be recorded and transmitted.

When Vermont subpoenaed claims data from the Liberty Mutual plan's third-party administrator, this suit was commenced in the United States District Court for the District of Vermont (Sessions, *J.*). Liberty Mutual sought a declaration that the Employee Retirement Income Security Act of 1974 ("ERISA") preempts the Vermont statute and regulation. The district court granted summary judgment in favor of Vermont.

The ERISA preemption clause is not self-reading and ERISA preemption doctrine is not static. The early judicial consensus, based on the broad wording of the preemption clause (and legislative history), was to construe preemption broadly. More recent precedent has pulled back by setting a rebuttable presumption against preemption of state health care regulations. Two constants, however, remain: (1) recognition that ERISA's preemption clause is intended to avoid a multiplicity of burdensome state requirements

for ERISA plan administration; and (2) acknowledgment that "reporting" is a core ERISA administrative function. These two considerations lead us to conclude that the Vermont law, as applied to compel the reporting of Liberty Mutual plan data, is preempted. We therefore reverse and remand for entry of judgment in favor of Liberty Mutual.

BACKGROUND

I

The Vermont statute establishes and provides for the maintenance of "a unified health care database." Vt. Stat. Ann. tit. 18, § 9410(a)(1). The database "enable[s]" the State's Department of Banking, Insurance, Securities and Health Care Administration ("Department")[1] "to carry out [its] duties . . . , including":

> (A) determining the capacity and distribution of existing resources;
>
> (B) identifying health care needs and informing health care policy;
>
> (C) evaluating the effectiveness of intervention programs on improving patient outcomes;

[1] The Department is now called the Department of Financial Regulation. Many of the Department's health care database responsibilities were recently transferred to Vermont's Green Mountain Care Board. *See id.* § 9410.

> (D) comparing costs between various treatment settings and approaches;
>
> (E) providing information to consumers and purchasers of health care; and
>
> (F) improving the quality and affordability of patient health care and health care coverage.

Id.

To populate the database, the statute requires "[h]ealth insurers, health care providers, health care facilities, and governmental agencies" to "file reports, data, schedules, statistics, or other information," as the Department deems necessary, at the time and place and in the manner the Department requires. *Id.* at § 9410(c)-(d). The statute authorizes the Department to require the filing of "health insurance claims and enrollment information used by health insurers" and "any other information relating to health care costs, prices, quality, utilization, or resources." *Id.* at § 9410(c).

Knowing and willful failure to comply is punishable by penalty of not more than $10,000 per violation. *See id.* at § 9410(g).

In 2008, the Department promulgated a regulation to implement the statute and create the Vermont Healthcare Claims Uniform Reporting and Evaluation System (the "Reporting System"). *See* Regulation H-2008-01, 21-040-021 Vt. Code R. § 1 ("Regulation H-2008-01"). The regulation requires reporting of

myriad categories of claims data. *See infra* 26-29. "Health Insurers" are required to "regularly submit medical claims data, pharmacy claims data, member eligibility data, provider data, and other information relating to health care provided to Vermont residents and health care provided by Vermont health care providers and facilities to both Vermont residents and non-residents in specified electronic format to the Department for each health line of business . . . per the data submission requirements contained in" appendices to the regulation. Regulation H-2008-01 § 4(D).

A "[h]ealth insurer" is defined broadly to include "any health insurance company, . . . third party administrator, . . . and any entity conducting administrative services for business or possessing claims data, eligibility data, provider files, and other information relating to health care provided to Vermont residents or by Vermont health care providers and facilities." *Id.* § 3(X).

Begging the preemption question, the term "[h]ealth insurer" "may also include, *to the extent permitted under federal law,* any administrator of an insured, self-insured, or publicly funded health care benefit plan offered by public and private entities." *Id.* (emphasis added). A health insurer with 200 or more enrolled or covered members in each month during a calendar year is designated a "Mandated Reporter." *Id.* § 3(Ab). All other entities are "Voluntary Reporter[s]." *Id.* § 3(As).

The Department makes the collected data "available as a resource for insurers, employers, providers, purchasers of health care, and state agencies to continuously review health care utilization, expenditures, and performance in Vermont." Vt. Stat. Ann. tit. 18, § 9410(h)(3)(B). The Department decides "the extent" of such disclosure "allowed by HIPAA," the federal Health Insurance Portability and Accountability Act of 1996, *id.,* and maintains the "confidentiality code" by which filed information "is handled in an ethical manner," *id.* § 9410(f). "[D]irect personal identifiers," such as name, address, and Social Security number, may not be publicly disclosed. *Id.* § 9410(h)(3)(D).

Sixteen other states collect health care data for their own health care claims databases. J.A. 368-74 (State Health Reporting Laws Summary Table). Data submission requirements vary. Some states provide only for voluntary reporting. *See id.* Some expressly exclude self-insured employee plan data from their database reporting laws. *See id.* The majority, however, follow Vermont in requiring such plans to report claims data. *See id.*

II

Liberty Mutual Insurance Co. is the administrator and named fiduciary of a health plan (the "Plan") that provides benefits to 137 individuals in Vermont and to over 80,000 individuals nationwide. The Plan is "self-insured" or "self-funded," *i.e.,* health care claims are paid from Liberty Mutual's general assets.

Plan documents provide that the "Plan has been established for the exclusive benefit of Participants and except as otherwise provided . . . , all contributions under the Plan may be used only for such purpose." J.A. 39. The documents also represent that medical records, such as those related to risk factor screening, are kept "strictly confidential." J.A. 71-72. The Plan represents, however, that it "shall comply with all other state and federal law to the extent not preempted by ERISA and to the extent such laws require compliance by the Plan." J.A. 41.

Like many self-insured employer health plans, the Plan uses a third-party administrator ("TPA"). Blue Cross Blue Shield of Massachusetts, Inc. ("Blue Cross"), as the Plan's TPA for Vermont participants, does claims-handling: processing, review, and payment. Under its contract with Liberty Mutual, any information transferred to Blue Cross must be used solely for the purpose of administering the Plan, and Blue Cross auditors must guard against unauthorized disclosure of health care information. *See* J.A. 57-58. Liberty Mutual itself is a Voluntary Reporter because it has fewer than 200 covered members in Vermont (and has presumably decided not to volunteer); but because Blue Cross qualifies as a Mandated Reporter and possesses the Plan's claims data, the reporting of its data is mandatory.

In August 2011, Vermont issued a subpoena demanding that Blue Cross supply the Plan's "[e]ligibility files," "[m]edical claims files," and "[p]harmacy claims files" and threatened that noncompliance

might result in fines and a suspension of Blue Cross's authority to do business. J.A. 24-25. Liberty Mutual instructed Blue Cross not to comply and filed this suit, seeking (1) a declaration that ERISA preempts the Vermont statute and regulation; and (2) an injunction blocking enforcement of the subpoena. Vermont agreed to stay enforcement of the subpoena pending judicial resolution of the ERISA preemption question.

In dueling motions, Vermont sought to dismiss the complaint for lack of standing and for failure to state a claim, and Liberty Mutual moved for summary judgment. With the consent of the parties, the district court treated the motions as cross-motions for summary judgment. *See Liberty Mut. Ins. Co. v. Kimbell,* No. 2:11-cv-204, 2012 WL 5471225, at *1 (D. Vt. Nov. 9, 2012).

The court concluded that Liberty Mutual had Article III standing but that ERISA did not preempt the Vermont statute and regulation and that Vermont was therefore entitled to summary judgment. *See id.*

DISCUSSION

I

We agree with the district court that Liberty Mutual has standing to challenge the subpoena

issued to Blue Cross.[2] Liberty Mutual has demonstrated "the irreducible constitutional minimum of standing": (1) "an invasion of a legally protected interest which is (a) concrete and particularized; and (b) actual or imminent, not conjectural or hypothetical"; (2) "a causal connection between the injury and the conduct complained of"; and (3) that the injury will likely be redressed by a favorable decision. *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560-61 (1992) (footnote, citations, and internal quotation marks omitted).

It is of no moment that the subpoena was issued to Blue Cross and not directly to Liberty Mutual. The TPA agreement provides that Liberty Mutual will hold Blue Cross harmless for any financial charges "arising from or in connection with" the Plan. J.A. 54-55. Liberty Mutual therefore faces a choice between (1) allowing Blue Cross to turn over the Plan's data in what Liberty Mutual considers a violation of its duties as Plan administrator and fiduciary; or (2) directing non-compliance, and indemnifying Blue Cross for the ensuing civil penalties. Either way, under *Lujan,* Liberty Mutual suffers a redressable injury-in-fact as a direct result of Vermont's threatened, imminent action.

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[2] The parties have not briefed the standing issue on appeal, but Article III standing "is the threshold question in every federal case, determining the power of the court to entertain the suit." *Warth v. Seldin,* 422 U.S. 490, 498 (1975).

II

We review *de novo* the grant of summary judgment on the preemption question. *See, e.g., Wrobel v. Cnty. of Erie,* 692 F.3d 22, 27 (2d Cir. 2012). Summary judgment is appropriate if the record shows "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "[W]e may reverse the grant of summary judgment and order judgment for the non-moving party if we find undisputed support in the record entitling the non-moving party to judgment as a matter of law." *New England Health Care Emps. Union v. Mount Sinai Hosp.,* 65 F.3d 1024, 1030 (2d Cir. 1995).

A

ERISA's comprehensive regulatory scheme governs most employee benefit plans, including self-insured health plans. *See* 29 U.S.C. § 1003. ERISA requires plan administrators to file annually with the Department of Labor reports detailing financial and actuarial information. *See id.* §§ 1021-1024. The Department of Labor is authorized "to undertake research and surveys and in connection therewith to collect, compile, analyze and publish data, information, and statistics relating to employee benefit plans." *Id.* § 1143. ERISA broadly preempts "any and all State laws insofar as they may now or hereafter *relate to any employee benefit plan*." *Id.* § 1144(a) (emphasis added). With remarkable consistency, the

legislative history reflects that this broad wording was purposeful: it was intended to eliminate the threat of a multiplicity of conflicting or inconsistent state laws,[3] and to achieve broad preemptive effect in the areas of record-keeping, reporting, and disclosure.[4]

Vermont argues – and the district court agreed – that Congress could not have intended broad preemption of state reporting laws because the same Congress also passed the National Health Planning and

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[3] *See* 120 Cong. Rec. 29197 (1974) (Statement of Rep. Dent) ("I wish to make note of what is to many the crowning achievement of this legislation, the reservation to Federal authority the sole power to regulate the field of employee benefit plans. With the preemption of the field, we round out the protection afforded participants by eliminating the threat of conflicting and inconsistent State and local regulation."); *id.* at 29933 (Statement of Sen. Williams) (discussing "inten[t] to preempt the field for Federal regulations, thus eliminating the threat of conflicting or inconsistent State and local regulation of employee benefit plans" and stating that "[t]his principle is intended to apply in its broadest sense to all actions of State or local governments, or any instrumentality thereof, which have the force or effect of law").

[4] *See* S. Rep. No. 93-127, at 35 (1973), *reprinted in* 1974 U.S.S.C.A.N. 4838, 4871 ("Because of the interstate character of employee benefit plans, the Committee believes it essential to provide for a uniform source of law in the areas of vesting, funding, insurance and portability standards, for evaluating fiduciary conduct, and *for creating a single reporting and disclosure system in lieu of burdensome multiple reports.*" (emphasis added)); H.R. Rep. No. 93-533, at 17 (1973), *reprinted in* 1974 U.S.S.C.A.N. 4639, 4655 (virtually the same); *see also* 120 Cong. Rec. 29942 (1974) (Statement of Sen. Javits) ("In view of Federal preemption, State laws compelling disclosure from private welfare or pension plans . . . will be superseded.").

Resources Development Act of 1974 ("NHPRDA"). The NHPRDA provided for the establishment of state health planning agencies and authorized these agencies to "assemble and analyze data concerning" health; health care delivery, resources, and use; and related environmental factors. *See* Pub. L. No. 93-641, 88 Stat. 2225, at § 1513(b) (1975). The Supreme Court consulted the NHPRDA to decide ERISA preemption in a case in which the NHPRDA expressly contemplated a state regulatory measure. *See N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.,* 514 U.S. 645, 665-67 (1995). Here, however, the NHPRDA is not similarly indicative.[5] And if there were tension between NHPRDA and ERISA, it was relieved in 1986 when the NHPRDA was repealed.

B

The Supreme Court, and this Court, initially applied ERISA preemption as broadly as the statutory phrase ("relate to any employee benefit plan") seemed to require.

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[5] The NHPRDA's encouragement of state data collection is not necessarily inconsistent with ERISA's preemptive reach. A lot of data can be collected from health care providers, and from health care payers other than ERISA plans. Nothing in the NHPRDA compels the conclusion that, contrary to every indication in ERISA's text and history, Congress intended to allow a multiplicity of state record-keeping and reporting requirements for self-insured employee plans.

As explained in *Shaw v. Delta Air Lines, Inc.,* the "breadth of [ERISA's] pre-emptive reach is apparent from that section's language." 463 U.S. 85, 96 (1983); *see id.* at 98 ("Congress used the words 'relate to' . . . in their broad sense.").[6] *Shaw* formulated the modern ERISA preemption test: a state law is preempted if "it *[1] has a connection with* or *[2] reference to* [an ERISA] plan." *Id.* at 96-97 (emphases added). The Court treated as obvious that ERISA preempted "state laws dealing with the subject matters covered by ERISA – *reporting, disclosure,* fiduciary responsibility, and the like." *Id.* at 98 (emphases added). The open question was whether preemption went *beyond* these core areas, and the Court held it did. *See id.* at 96-97. The one note of caution in *Shaw* was consigned to a footnote:

> Some state actions may affect employee benefits plans in too tenuous, remote, or peripheral a manner to warrant a finding that the law "relates to" the plan. Cf. *Am. Tel. & Tel. Co. v. Merry,* 592 F.2d 118, 121 (CA2 1979) (state garnishment of a spouse's pension income to enforce alimony and support orders is not pre-empted). The present litigation plainly does not present a border-line question, and we express no views about

[6] That interpretation was supported by ERISA's exemption for generally applicable state criminal statutes, an exemption that would be unnecessary if preemption "applied only to state laws dealing specifically with ERISA plans." *Shaw,* 463 U.S. at 98 (discussing 29 U.S.C. § 1144(b)(4)).

> where it would be appropriate to draw the line.

Id. at 100 n.21.

For another decade, the Supreme Court and this Court followed *Shaw* and repeatedly emphasized the broad reach of ERISA preemption. *See, e.g., FMC Corp. v. Holliday,* 498 U.S. 52, 58 (1990) ("The pre-emption clause is conspicuous for its breadth."); *Gen. Elec. Co. v. N.Y. State Dep't of Labor,* 891 F.2d 25, 29 (2d Cir. 1989) ("ERISA was intended to have a 'sweeping preemptive effect in the employee benefit plan field.' Congress intended ERISA to occupy and regulate the field of employee benefit plans." (citation omitted)). The threat of conflicting state and local regulation was consistently cited as a paramount reason for preemption: Preemption "was intended to ensure that plans and plan sponsors would be subject to a uniform body of benefits law; the goal was to minimize the administrative and financial burden of complying with conflicting directives among States or between States and the Federal Government." *Ingersoll-Rand Co. v. McClendon,* 498 U.S. 133, 142 (1990); *see Fort Halifax Packing Co. v. Coyne,* 482 U.S. 1, 10 (1987) ("We have not hesitated to enforce ERISA's pre-emption provision where state law created the prospect that an employer's administrative scheme would be subject to conflicting requirements. . . . Such a situation would produce considerable inefficiencies, which the employer might choose to offset by lowering benefit levels."); *Howard v. Gleason Corp.,* 901 F.2d 1154, 1157 (2d Cir. 1990) ("[T]he express pre-emption

provisions of ERISA are deliberately expansive, and designed to establish pension plan regulation as exclusively a federal concern in order to afford employers the advantages of a uniform set of administrative procedures governed by a single set of regulations." (citations and internal quotation marks omitted)).

These cases specifically re-emphasized that "reporting" and "disclosure" are core ERISA functions subject to a uniform federal standard. *See Ingersoll-Rand,* 498 U.S. at 137 ("[ERISA] sets various uniform standards, including rules concerning reporting, disclosure, and fiduciary responsibility. . . ."); *FMC Corp.,* 498 U.S. at 58 (listing "reporting" and "disclosure" as "subject matters covered by ERISA").

The Supreme Court has explained the importance of having uniform federal record-keeping and reporting requirements:

> [The legislative history] reflect[s] recognition of the administrative realities of employee benefit plans. An employer that makes a commitment systematically to pay certain benefits undertakes a host of obligations, such as determining the eligibility of claimants, calculating benefit levels, making disbursements, monitoring the availability of funds for benefit payments, and *keeping appropriate records in order to comply with applicable reporting requirements.* The *most efficient way to meet these responsibilities is to establish a uniform administrative scheme,* which provides a set of standard procedures to guide processing of claims and disbursement

> of benefits. Such a system is *difficult to achieve, however, if a benefit plan is subject to differing regulatory requirements in differing States. A plan would be required to keep certain records in some States but not in others*; to make certain benefits available in some States but not in others; to process claims in a certain way in some States but not in others; and to comply with certain fiduciary standards in some States but not in others.

Fort Halifax, 482 U.S. at 9 (emphases added).

Liberty Mutual places great weight on the Supreme Court's summary affirmance of one of these early preemption cases, *Standard Oil Co. v. Agsalud,* 633 F.2d 760, 763 (9th Cir. 1980). We need not rest our ruling on that case or on so perfunctory a disposition as summary affirmance.[7] At the same time, it is

[7] The district court in *Agsalud* held that a Hawaii law (1) requiring workers to be covered by a comprehensive prepaid health care plan and (2) imposing "certain reporting requirements which differ[ed] from those of ERISA," was preempted. 442 F. Supp. 695, 696, 706-07 (N.D. Cal. 1977). Though the ruling rested mainly on the state's comprehensive prepaid plan requirement, the court added that the ERISA preemption clause "was intended at the very least to preempt state laws regulating disclosure [and] reporting." *Id.* at 706 n.11. The Ninth Circuit agreed with the district court, 633 F.2d 760, 763 (9th Cir. 1980), and the Supreme Court summarily affirmed, *Agsalud v. Standard Oil Co.,* 454 U.S. 801 (1981). However, "the precedential effect of a summary affirmance extends no further than the precise issues presented and necessarily decided by those actions." *Anderson v. Celebrezze,* 460 U.S. 780, 784 n.5 (1983) (internal quotation marks omitted).

telling that when Congress amended ERISA in 1983 "to exempt from pre-emption certain provisions of the Hawaii Act," it "did not exempt from pre-emption those portions of the law dealing with reporting, disclosure, and fiduciary requirements." *Fort Halifax,* 482 U.S. at 13 n.7; *see* H.R. Rep. No. 97-984, at 18 (Dec. 21, 1982) (Conf. Rep.) ("The provision continues Federal preemption of State law with respect to matters governed by the reporting and disclosure and the fiduciary responsibility provisions of ERISA. . . .").

C

The Supreme Court's 1995 decision in *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.* marked something of a pivot in ERISA preemption. *See* 514 U.S. 645 (1995). The Court began "with the starting presumption that Congress does not intend to supplant state law," especially if the "state action [occurs] in fields of traditional state regulation," like health care.[8] *Id.* at

[8] The dissent relies on this presumption. *See* Dissenting Op. at 4-5. We acknowledge that the presumption applies when the state law "operates in a field that has been traditionally occupied by the States," and that "the historic police powers of the State include the regulation of matters of health and safety." *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund,* 520 U.S. 806, 814 (1997) (internal quotation marks omitted). However, state health data collection laws do not regulate the safe and effective provision of health care services, which is among the states' historic police powers. And collecting data can hardly be deemed "historic" – most such laws were enacted only within the last ten years. *See* J.A. 368-74. In any event, the Supreme Court has

(Continued on following page)

654-55. To preempt, a "clear and manifest purpose" by Congress is required. *Id.* at 655. Following on this presumption, the Court pulled back on its broad, literal reading of "relate to": if the phrase "were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course." *Id.*

Applying the two-part *Shaw* test in light of these new principles, the Court concluded that a state statute requiring hospitals to collect a surcharge from patients covered by commercial insurers was not preempted. *See id.* at 656. The Court explained that state law is preempted if it "mandate[s] employee benefit structures or their administration" or "provid[es] alternative enforcement mechanisms." *Id.* at 658. The state surcharge law withstood preemption in *Travelers* because it had no more than an "indirect economic influence" on ERISA plans, it did "not bind plan administrators to any particular choice and thus function as a regulation of an ERISA plan itself," and it did not "preclude uniform administrative practice or the provision of a uniform interstate benefit package if a plan wishes to provide one." *Id.* at 659-60.

The Court again recognized the central roles of reporting and disclosure: ERISA "controls the administration of benefit plans, as by imposing *reporting*

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repeatedly found the presumption overcome if the state laws "upset[ ] the deliberate balance central to ERISA," even if those laws "implement policies and values lying within the traditional domain of the States." *Boggs v. Boggs,* 520 U.S. 833, 840, 854 (1997).

and disclosure mandates." *Id.* at 651 (emphasis added) (citation omitted). "Congress's extension of pre-emption to all state laws relating to benefit plans was meant to sweep *more* broadly than state laws dealing with the subject matters covered by ERISA, *reporting, disclosure,* fiduciary responsibility, and the like." *Id.* at 661 (emphases added) (internal quotation marks and brackets omitted).

Applying *Travelers,* cases conclude that state laws having only an "indirect economic effect on ERISA plans" lack sufficient "connection with" or "reference to" an ERISA plan to "trigger ERISA preemption." *New England Health Care Emps. Union v. Mount Sinai Hosp.,* 65 F.3d 1024, 1030-33 (2d Cir. 1995); *see also De Buono v. NYSA-ILA Med. & Clinical Servs. Fund,* 520 U.S. 806, 809 (1997) (state hospital tax not preempted); *NYS Health Maint. Org. Conference v. Curiale,* 64 F.3d 794, 801-03 (2d Cir. 1995) ("[O]nly link [state surcharge law] has with ERISA plans is its indirect effect on rate diversification among insurers."). Nevertheless, the Supreme Court teaches that *Travelers* and its progeny do not disturb the long-standing principle that "state statutes that mandate[] employee benefit structures *or their administration*" have a "connection with" ERISA plans and are therefore preempted. *Cal. Div. of Labor Standards Enforcement v. Dillingham Constr.,* 519 U.S. 316, 328 (1997) (emphasis added) (internal quotation marks omitted). Like *Travelers* itself, later cases reiterate that "ERISA is expressly concerned" with "reporting, disclosure, fiduciary responsibility, and the like." *Id.*

at 330 (internal quotation marks omitted); *see also Boggs v. Boggs,* 520 U.S. 833, 841 (1997); *Plumbing Indus. Bd. v. E.W. Howell Co.,* 126 F.3d 61, 66 (2d Cir. 1997).

The use of preemption to avoid proliferation of state administrative regimes also remains a vital feature of the law. "[D]iffering state regulations affecting an ERISA plan's system for *processing claims* and paying benefits impose precisely the burden that ERISA pre-emption was intended to avoid." *Egelhoff v. Egelhoff,* 532 U.S. 141, 150 (2001) (emphasis added) (internal quotation marks omitted); *see Romney v. Lin,* 94 F.3d 74, 80 (2d Cir. 1996) ("basic purpose" of ERISA preemption is to "avoid a multiplicity of regulation in order to permit the nationally uniform administration of employee benefit plans").

It is true that this Court's three most recent cases focus primarily on "the relationships among the core ERISA entities," and caution against preemption of generally applicable state laws. *See Stevenson v. Bank of N.Y. Co.,* 609 F.3d 56, 61 (2d Cir. 2010); *Hattem v. Schwarzenegger,* 449 F.3d 423, 429-31 (2d Cir. 2006); *Gerosa v. Savasta & Co.,* 329 F.3d 317, 324 (2d Cir. 2003). But these cases involve either a state income tax with only indirect economic effects (the kind of law *Travelers* expressly permits), *see Hattem,* 449 F.3d at 425, or state law causes of action that have "little to do with the conduct of the plan," *Gerosa,* 329 F.3d at 328; *see also Stevenson,* 609 F.3d at 61 (noting that state law suit did not implicate "actual administration" of the plan). They do not

purport to save state laws that subject plans to "sets of inconsistent state obligations" or that "tend to control or supersede central ERISA functions." *Gerosa,* 329 F.3d at 324, 328.

When this Court has allowed a state reporting requirement to withstand preemption, as it has in two post-*Travelers* cases, the requirement:

> (1) imposed no "particular form" of record-keeping and created burdens "so slight" as to "create[ ] no impediment to an employer's adoption of a uniform benefit administration scheme," *Burgio & Campofelice, Inc. v. NYS Dep't of Labor,* 107 F.3d 1000, 1009 (2d Cir. 1997) (internal quotation marks omitted); or
>
> (2) "sought information readily obtainable from an employer" without specifying "a particular form of record-keeping," *HMI Mech. Sys., Inc. v. McGowan,* 266 F.3d 142, 150-51 (2d Cir. 2001).

In effect, these cases adhere to the intact pre-*Travelers* principle against preemption of laws "creat[ing] no impediment to an employer's adoption of a uniform benefit administration scheme," *Fort Halifax,* 482 U.S. at 14, and with "too tenuous, remote, or peripheral" an effect on employee benefit plans, *Shaw,* 463 U.S. at 100 n.21. Thus *HMI* (which Vermont relies on heavily) cautioned that state subpoenas would indeed be "overbroad to the extent that they seek the amount of benefits that employees receive" or "examin[e] employer contributions on a benefit by benefit basis." *HMI,* 266 F.3d at 151.

D

We hold that the reporting requirements of the Vermont statute and regulation have a "connection with" ERISA plans (though no "reference to" them[9]) and are therefore preempted as applied. Our holding is supported by the principle (undisturbed in *Travelers*) that "reporting" is a core ERISA function shielded from potentially inconsistent and burdensome state regulation.[10]

ERISA preempts "state laws dealing with the subject matters covered by ERISA – *reporting, disclosure,* fiduciary responsibility, and the like." *Shaw,* 463 U.S. at 98 (emphases added). "[R]eporting" is necessarily a function distinct from the disclosure that administrators provide beneficiaries; otherwise "reporting"

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[9] The Vermont statute and regulation lack "reference to" an ERISA plan because they apply to all health care payers and do not act "exclusively upon ERISA plans." *Dillingham,* 519 U.S. at 325; *Travelers,* 514 U.S. at 656. A "connection with" an ERISA plan is sufficient, however, for preemption. *Shaw,* 463 U.S. at 96-97 (setting out disjunctive test).

[10] It is of no moment that the law is being applied to, and the subpoena targeted at, Liberty Mutual's TPA rather than Liberty Mutual itself. *See Pharm. Care Mgmt. Ass'n v. Dist. of Columbia,* 613 F.3d 179, 182 (D.C. Cir. 2010) (holding ERISA preempts state law provisions "insofar as they apply to a pharmaceutical benefits manager . . . under contract with an employee benefit plan (EBP) because they 'relate to' an EBP"). We agree with the D.C. Circuit that "the objective of uniformity in plan administration" is not "for some reason inapplicable simply because a plan has contracted with a third party to provide administrative services." *Id.* at 185.

would be subsumed by "disclosure" and rendered superfluous. Rather, "reporting" entails what Vermont requires be done: plan record-keeping, and filing with a third-party.

But whatever the scope of plan "reporting," Vermont cannot deny that that is what it is seeking. The relevant database is called the "Vermont Healthcare Claims Uniform *Reporting* and Evaluation System" and the operative section of the regulation is titled "*Reporting Requirements.*"[11] Regulation H-2008-01 §§ 3(Ar), 4 (emphases added).

Not every state law imposing a reporting requirement is preempted. *Burgio* and *HMI* allow a slight reporting burden to be laid on plans, consistent with the preemption rule tolerating laws that "create[ ] no impediment to an employer's adoption of a uniform benefit administration scheme," *Fort Halifax,* 482 U.S. at 14, and with "too tenuous, remote, or peripheral" an effect on employee benefit plans, *Shaw,* 463 U.S. at 100 n.21.

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[11] The dissent argues that the "reporting requirement imposed by the Vermont statute differs in kind from the 'reporting' that is required by ERISA and therefore was not the kind of state law Congress intended to preempt." Dissenting Op. at 1. But the conclusion does not follow from the premise. To the contrary: A hodge-podge of state reporting laws, each *more* onerous than ERISA's uniform federal reporting regime, and seeking different and additional data, is exactly the threat that motivates ERISA preemption.

But the reporting mandated by the Vermont statute and regulation is burdensome, time-consuming, and risky. Even considered alone, the Vermont scheme triggers preemption; considered as one of several or a score of uncoordinated state reporting regimes, it is obviously intolerable.

A quick overview of the Reporting System is telling:

- Plans must periodically report:

  (1) "medical claims data" "composed of service level remittance information for all non-denied adjudicated claims for each billed service including, but not limited to member demographics, provider information, charge/payment information, and clinical diagnosis and procedure codes, and . . . includ[ing] all claims related to behavioral or mental health";

  (2) "pharmacy claims data" "containing service level remittance information from all non-denied adjudicated claims for each prescription including, but not limited to: member demographics[,] provider information[,] charge/payment information[,] and national drug codes";

  (3) "member eligibility data" "containing demographic information for each individual member eligible for medical or pharmacy benefits for one or more days of coverage at any time during the reporting month";

(4) and any "other information relating to health care provided to Vermont residents and health care provided by Vermont health care providers and facilities to both Vermont residents and non-residents . . . for each health line of business." Regulation H-2008-01 §§ 3-4.

- Plans must report their data frequently. Thus plans with 500 to 1,999 covered members must report *quarterly* and plans with 2,000 or more covered members must report *monthly*. *See id.* § 6(1). Compare this to ERISA, which requires a single report *annually*. *See* 29 U.S.C. § 1021.
- Data must be coded under the appropriate source code system. *See* Regulation H-2008-01 § 5(A)(5)(a). Sixteen source code systems are provided, including the "Admission Source Code" ("[a] variety of codes explaining who recommended admission to a medical facility") and the "International Classification of Diseases, 9th Revision, Clinical Modification" code ("describes the classification of morbidity and mortality information for statistical purposes and for the indexing of hospital records by disease and operations"). *Id.* Appendix A.
- "Individual data elements, data types, field lengths, field description/code assignments, and mapping locators" for each file must conform to specified requirements. *Id.* § 5(B). Fields include "Admission Hour" and "Discharge Hour," thirteen "Diagnosis" fields,

three "Procedure" fields, and the "Drug Name" and "Quantity Dispensed". *Id.* Appendices C-1-E-2.

- "[T]he social security number of the member/subscriber and the subscriber and member names" must be encrypted prior to submission by "utilizing a standard encryption methodology provided." *Id.* § 5(A)(5)(b). (Encryption is not required for other data fields.)

And nothing prevents the Department from changing these myriad requirements from time to time, so long as the Department complies with the broad mandate of the statute.

The confidentiality provisions of the Vermont scheme are complex but loose, and impair or (at least) reassign the obligation in the Plan documents to keep medical records strictly confidential, as well as the undertaking by Blue Cross as TPA to use information solely for Plan administration purposes and to prevent unauthorized disclosure.[12] The regulation specifically contemplates "access to health care claims data sets and related information" by "persons other than

[12] Whether disclosure to Vermont is authorized under the Plan documents may turn on whether Vermont law creates authorization, because the Plan undertakes to comply with state law; but compliance is allowed only "to the extent not preempted by ERISA," a limitation that leaves the Plan and the TPA in a complex and expensive legal muddle.

the Department." *Id.* § 8. Each data field is classified into one of three "use and release" categories:

> (1) "Unavailable Data Elements": not available for general use and release.
>
> (2) "Restricted Data Elements": only available for use and release as part of a "Limited Use Research Health Care Claims Data Set" approved by the Department. These elements, and information that can be derived from these elements, include the member's city and zip code, the admission and discharge dates and hours, and the service provider and pharmacy names.
>
> (3) "Unrestricted Data Elements": "available for general use and public release. . . . upon written request." These publicly available elements, and information that can be derived from these elements, include the member's gender, age, medical coverage, prescription drug coverage, and diagnosis; the type of procedure; the service provider's speciality and zip code; and the name and price of any drugs prescribed.

Id. § 8 & Appendices J-1-J-14. Specific as these categories are, they may be illusory, because the Department can ease public release restrictions on data that is currently restricted or unavailable, so long as "direct" personal identifiers are not published and the data is (in the Department's opinion) handled in an "ethical manner." Vt. Stat. Ann. tit. 18, § 9410(e)-(f), (h)(3)(D).

Since other states can impose their own regimes for reporting – and many do – these burdens and risks must be multiplied.

The trend toward narrowing ERISA preemption does not allow one of ERISA's core functions – reporting – to be laden with burdens, subjected to incompatible, multiple and variable demands, and freighted with risk of fines, breach of duty, and legal expense.[13]

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[13] The dissent draws a "distinction between general administration and administration of plans, claims, and benefits" and concludes that ERISA preemption doctrine does not reach state reporting laws that implicate the former. Dissenting Op. at 14. Essentially, the dissent would preempt state reporting laws only if they require plans to submit financial statements. The dissent's view of ERISA plan "administration" and "reporting" is unduly narrow.

The overview of requirements (set out above) makes clear that Vermont requires ERISA plans to record, in specified format, massive amounts of claims information and to report that information to third parties, creating significant (and obvious) privacy risks and financial burdens that will be passed from the TPA to the Plan and from the Plan to the beneficiaries. That is not a proper allocation of plan assets. *See* 29 U.S.C. § 1104(a)(1)(A) ("[A] fiduciary shall discharge his duties with respect to a plan solely in the interest of the participants and beneficiaries and . . . for the exclusive purpose of . . . providing benefits to participants and their beneficiaries; and . . . defraying reasonable expenses of administering the plan[.]"). Modest financial burdens may be tolerable when the state laws imposing them do not directly implicate an ERISA core administrative concern. But the statute and regulation here require reporting of health claims, pharmacy claims, *etc.,* information about the essential functioning of employee health plans.

CONCLUSION

For the foregoing reasons, we reverse and remand with instructions to enter judgment for Liberty Mutual.

STRAUB, *Circuit Judge*, dissenting in part and concurring in part:

I respectfully dissent in part and concur in part.

I concur with part I of the discussion section of the majority opinion finding that Liberty Mutual has standing. For the reasons that follow, I dissent from the majority's holding that the Vermont statute is preempted by ERISA.

The majority finds that the burden imposed by the Vermont reporting requirement warrants preemption of the statute. This conclusion falters for two primary reasons. First, the reporting requirement imposed by the Vermont statute differs in kind from the "reporting" that is required by ERISA and therefore was not the kind of state law Congress intended to preempt. Second, Liberty Mutual has failed to show any actual burden, much less a burden that triggers ERISA preemption. Rather, the Vermont statute, like others we have previously upheld, does not interfere with an ERISA plan's administration of benefits. For these reasons, our precedent and that of the Supreme Court do not support the conclusion that the Vermont statute's reporting requirements pose the sort of threat to "the nationally uniform administration of

employee benefit plans" that would trigger preemption. *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.,* 514 U.S. 645, 657 (1995) (hereinafter "*Travelers* ").

Looking at the objectives of ERISA and the impact of the Vermont statute on ERISA plans, as we must in order to determine whether the statute has an improper "connection with" ERISA plans, I conclude that this is not the type of statute that Congress intended to preempt.

ANALYSIS

The preemption clause of the ERISA statute provides that, with certain exceptions not relevant here, ERISA "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a). The Supreme Court has stated that the "basic thrust of the preemption clause . . . was to avoid a multiplicity of regulation in order to permit the nationally uniform administration of employee benefit plans." *Travelers,* 514 U.S. at 657. "Pre-emption does not occur, however, if the state law has only a 'tenuous, remote, or peripheral' connection with covered plans, as is the case with many laws of general applicability." *Burgio & Campofelice, Inc. v. N.Y. State Dep't of Labor,* 107 F.3d 1000, 1008 (2d Cir. 1997) (internal quotations marks omitted) (quoting *Shaw v. Delta Air Lines, Inc.,* 463 U.S. 85, 100 n.21 (1983)).

"Two kinds of state laws relate to ERISA for purposes of preemption: those that mandate employee benefit structures or their administration, and those that provide alternative enforcement mechanisms." *HMI Mech. Sys., Inc. v. McGowan,* 266 F.3d 142, 149 (2d Cir. 2001) (internal quotation marks and brackets omitted). The Vermont statute does neither. We have noted that courts are "reluctant to find that Congress intended to preempt state laws that do not affect the relationships among" "the core ERISA entities: beneficiaries, participants, administrators, employers, trustees and other fiduciaries, and the plan itself." *Gerosa v. Savasta & Co.,* 329 F.3d 317, 324 (2d Cir. 2003). The Vermont statute does not even arguably regulate these relationships. Moreover, the Vermont statute does not impose regulations on how plans are to be run or how benefits are to be administered.

Yet the majority takes up Liberty Mutual's invitation to give the term "reporting" its broadest meaning, and finds the statute is preempted because "reporting" is a "core ERISA function shielded from potentially inconsistent and burdensome state regulation." (Maj. Op. at 24-25) While it is certainly true that ERISA's core areas include "reporting, disclosure, [and] fiduciary responsibility," *Shaw,* 463 U.S. at 98, and that "state laws that would tend to control or supersede central ERISA functions . . . have typically been found to be preempted," *Gerosa,* 329 F.3d at 324, the majority's argument misses the nuance of what "reporting" means in the context of ERISA, and

ignores the case law's focus on whether the *administration of benefits to beneficiaries* is impacted, an issue on which there is no showing.

A. Traditional State Regulation of Health Care and the Presumption Against Preemption

The majority's finding, hidden in a footnote, that the presumption against preemption does not apply here, flies in the face of clear Supreme Court precedent instructing us to begin with the "presumption that Congress does not intend to supplant state law." *Travelers,* 514 U.S. at 654-55. "[I]n cases like this one where federal law is said to bar state action in fields of traditional state regulation, we have worked on the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.* at 655 (internal citations and quotation marks omitted). This is because "nothing in the language of [ERISA] or the context of its passage indicates that Congress chose to displace general health care regulation, which historically has been a matter of local concern." *Id.* at 661.

The majority nonetheless holds that the presumption against preemption does not apply here because "state health data collection laws do not regulate the safe and effective provision of health care services." (Maj. Op. at 19 n.8) This contradicts the very Supreme Court precedent the majority relies upon: *DeBuono v. NYSA-ILA Medical and Clinical*

Services Fund, 520 U.S. 806 (1997). In that case, New York imposed a tax on patient services at various health care providers. 520 U.S. at 808. The Court applied the presumption, reasoning that although the New York law was "a revenue raising measure, rather than a regulation of hospitals, it clearly operates in a field that 'has been traditionally occupied by the States.'" *Id.* at 814. The Court further stated that the fact that the challenged law "targets only the health care industry . . . supports the application of the 'starting presumption' against pre-emption," because "the historic police powers of the State include the regulation of matters of health and safety." *Id.* at 814 & n.10. *DeBuono* is indistinguishable from the case at hand. Here, the Vermont statute "targets only the health care industry" and, even if it is not a regulation of health care entities, it certainly "operates in [the] field" of health and safety. Indeed, the stated purpose of the Vermont statute is to help improve health care quality. *See* Vt. Stat. Ann. tit. 18 § 9410(a)(1) (listing purposes, including "improving the quality and affordability of patient health care"). There should be no question, therefore, that the presumption applies here.

B. There is No Improper "Connection With" ERISA Plans

When analyzing whether ERISA preempts a state law, we apply the two-pronged *Shaw* test, as narrowed by *Travelers'* presumption against preemption. Under that test, we analyze whether a state law

has an impermissible "connection with" or "reference to" an ERISA plan. *See, e.g., Hattem v. Schwarzenegger,* 449 F.3d 423, 428 (2d Cir. 2006). Despite paying lip service to the *Shaw* test, the majority eschews a full analysis in favor of a talismanic recitation of the word "reporting."

I agree with the majority that because the Vermont statute requires data collection from entities other than ERISA plans, such as hospitals, health insurers, and pharmacy benefit managers, it "functions irrespective of the existence of an ERISA plan" and therefore does not make an improper "reference to" ERISA plans. *See Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.,* 519 U.S. 316, 328 (1997) (internal quotation marks and ellipsis omitted). The "connection with" prong, on which the majority hangs its hat, instructs us to examine both "the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive" and the "effect of the state law on ERISA plans." *See Egelhoff v. Egelhoff ex rel. Breiner,* 532 U.S. 141, 147 (2001) (internal quotation marks omitted); *see also HMI,* 266 F.3d at 148 ("Analyzing a state law's 'connection' with ERISA plans requires the courts to consider ERISA's objectives and the effect of the state law on ERISA plans."). This analysis leads to the conclusion that the Vermont statute is not preempted.

1. Objectives of ERISA

The objectives of the ERISA statute are not in dispute. Congress "enacted ERISA in 1974 to respond to growing concerns about the risk of employers defaulting on pension plans, which were increasingly widespread but little regulated." *See* Mallory Jensen, *Is ERISA Preemption Superfluous In the New Age of Health Care Reform?,* 2011 Colum. Bus. L. Rev. 464, 472 (2011) (internal footnotes omitted); *see also* Brendan S. Maher and Peter K. Stris, *ERISA and Uncertainty,* 88 Wash. U. L. Rev. 433, 440 n.29 (2010) ("Few dispute that the statute was passed, in part, as a response to several high-profile pension defaults that arose from company failures that devastated the pensions of many workers.") (citing J.A. Wooten, *The Most Glorious Story of Failure in the Business: The Studebaker-Packard Corp. & the Origins of ERISA,* 49 Buff. L. Rev. 683, 683-84 (2001)). Indeed, the statute itself declares that, in passing ERISA, Congress sought to

> protect interstate commerce and the interests of participants in employee benefit plans and their beneficiaries, by requiring the disclosure and reporting to participants and beneficiaries of financial and other information with respect thereto, by establishing standards of conduct, responsibility, and obligation for fiduciaries of employee benefit plans, and by providing for appropriate

> remedies, sanctions, and ready access to the Federal courts.

29 U.S.C. § 1001(b).[1]

These objectives are reflected in the ERISA reporting and disclosure requirements, which are concerned with the mismanagement of funds and failure to pay employee benefits, and seek information on plan assets or allocation. *See* 29 U.S.C. § 1023 (requiring publication of annual report to include a financial statement of assets and liabilities, changes in fund balance, disclosures about changes made in the plan, and financial commitments, including loans, leases, and transactions, and an actuarial statement). The plain language of the ERISA reporting requirements shows that they are limited to the furnishing of a summary plan description to plan participants and an annual report to the Secretary. *See* 29 U.S.C. §§ 1021-30. The former is essentially a plain-English summary of key plan terms, *id.* §§ 1021-22, while the

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[1] The Supreme Court has also noted that Representative Dent, the House sponsor of the legislation, "represented that ERISA's fiduciary standards 'will prevent abuses of the special responsibilities borne by those dealing with plans,'" and that the "disclosure and reporting requirements 'will enable both participants and the Federal Government to monitor the plans' *operations.*'" *Fort Halifax Packing Co. v. Coyne,* 482 U.S. 1, 15 (1987) (quoting 120 Cong. Rec. 29197 and 29935 (1974)). "Senator Williams, the Senate sponsor, stated that these fiduciary standards would safeguard employees from 'such abuses as self-dealing, imprudent investing, and misappropriation of plan funds.'" *Id.* (quoting 120 Cong. Rec. 29932).

latter is concerned with the financial soundness of the plan, *id.* § 1023. Thus, under ERISA, plans must report information that goes to the financial integrity of the plan.

It is important to recognize that, as Liberty Mutual conceded at oral argument (Tr. at 9), the "reporting" required by ERISA is wholly distinct from the reporting sought by Vermont. As the majority describes in some depth, the Vermont statute seeks information on medical claims data, the services that have been provided to beneficiaries, charges and payments for those services, and demographic information about those receiving the coverage. (Maj. Op. at 26-29) At bottom, the state seeks to collect the information it needs to fulfill its role of providing health care to its citizens. Vermont does not seek information on plan assets, and does not review the allocation or denial of benefits, *see* Reg. H-2008-01, 21-040-021 Vt. Code R. § 5A(8) ("Denied claims shall be excluded from all medical and pharmacy claims file submissions"), the topics on which ERISA requires reports. Indeed, the Secretary of Labor, who oversees the reporting requirements and is responsible for enforcing and administering Title I of ERISA, has advised us that the focus and purpose of Vermont's data collection is different from the reporting requirements in ERISA. *See Amicus* Secretary of Labor Br. at 12.

This contrast between the objectives and reporting requirements of ERISA and those of the Vermont

statute suggests that the Vermont statute is not of the type that Congress intended to preempt.

2. Effect of the Vermont Statute on ERISA Plans

We look next to the effect of the Vermont statute on ERISA plans. The Vermont statute asks for after-the-fact information which plan administrators, such as Blue Cross Blue Shield of Massachusetts ("BCBSMA"), already have in their possession. *See* Tr. at 7-8. Indeed, by all accounts BCBSMA is happy to provide the data Vermont has asked for, and it does so for other clients. Because Liberty Mutual possesses all the information Vermont seeks, the only alleged burden here is providing the data to Vermont in the requested format.

The majority finds that there is an obvious burden connected with the formats and requirements specified by Vermont, although it does not explain exactly how that burden manifests itself. Perhaps this is because Liberty Mutual has failed to provide any details or showing of the alleged burden, arguing only that "all regulations have their costs." Appellant's Br. at 28. *See also* Br. for *Amicus* Chamber of Commerce at 9 (increased steps required by a TPA to fulfill requirements) and 10 (arguing generally that additional requirements will "cost additional money").

In as much as this burden is a financial one, as Liberty Mutual suggests, we have stated clearly, as has the Supreme Court, that indirect financial costs

from a state law are not a concern unless they "preclude uniform administration practice or the provision of a uniform interstate benefit package." *Travelers,* 514 U.S. at 660. Indeed, our case law addressing statutes which impose added costs on ERISA plans states clearly that an indirect economic impact is sufficient to trigger preemption only if it "produce[s] such acute, albeit indirect, economic effects as to force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers." *Travelers,* 514 U.S. at 668; *see also Aetna Life Ins. Co. v. Borges,* 869 F.2d 142, 147 (2d Cir. 1989) (noting that "indirect economic and administrative effects are not substantial enough . . . to persuade us that this is the type of law Congress intended to preempt" and upholding Connecticut escheat law requiring Aetna to pay all unclaimed benefits to the State after three years, even though this would cause, *inter alia,* an increase in premiums to employers, lower benefits for employees, and lower profits for Aetna).[2] On the record before us, there is no basis to find that the Vermont statute would cause Liberty Mutual to increase its costs more than a *de minimus* amount to cover the cost of sending

[2] The majority claims that "modest financial burdens" are only "tolerable when the state laws imposing them do not directly implicate an ERISA core concern," (Maj. Op. at 31 n.13) without citing to any authority. This statement is directly contradicted by *Borges,* where financial burdens were acceptable despite implicating one of the most central ERISA concerns: the payment of benefits.

information to the state, much less that it would cause a fiduciary to change a plan in any way. *See DeBuono,* 520 U.S. at 815 (noting that many state laws of "general applicability" will "impose some burdens on the administration of ERISA plans, but nevertheless do not 'relate to' them within the meaning of" ERISA).

The majority also suggests the Vermont statute is inconsistent with ERISA because of its supposed inconsistencies with other state reporting regimes. To reach this conclusion, the majority relies on language from *Fort Halifax Packing Co. v. Coyne,* 482 U.S. 1 (1987), suggesting that ERISA preempts laws which create conflicting state record-keeping requirements. (Maj. Op. at 17-18) *Fort Halifax* involved a preemption challenge to a Maine statute requiring an employer to provide a one-time severance payment to employees under certain circumstances. 482 U.S. at 3. The Supreme Court found that the statute regulated employee benefits but did not regulate or establish an employee benefit "plan," and thus was not preempted by ERISA. *Id.* at 6-8.

The dicta in *Fort Halifax* on which the majority relies does not bear the weight the majority places upon it. To the extent *Fort Halifax* suggests that a state law may not require an ERISA plan to keep records it would not otherwise keep, that concern is not implicated here. The Vermont statute does not require plan administrators to keep any new records, it merely seeks access to the records that are already

kept. *Fort Halifax* does not say anything about when or how a state may demand access to existent records.

Moreover, the language in *Fort Halifax* describing the "administrative realities of employment benefit plans," does not relate to all administrative concerns, but rather to the repeatedly articulated concern that there be "nationally uniform administration *of employee benefit plans.*" *Travelers,* 514 U.S. at 657 (emphasis added). *See Fort Halifax,* 482 U.S. at 9 (suggesting it is most efficient for plans to have "a uniform administrative scheme, which provides a set of standard procedures to guide *processing of claims and disbursement of benefits.*" (emphasis added)).

The distinction between general administration and administration of plans, claims, and benefits is important. Many state laws may have an impact on the administration of an ERISA plan – for example, a work-place safety law, a prevailing wage law, or a law that requires companies to report employment data. Such laws may impose additional costs, or require additional administrative resources. But none of these laws impact *how benefits are administered to beneficiaries* and, therefore, they are not preempted by ERISA. *See, e.g., Dillingham,* 519 U.S. at 319 (upholding California prevailing wage law); *HMI,* 266 F.3d at 144 (upholding New York prevailing wage law); *Burgio,* 107 F.3d at 1003 (same). The reason for our focus on whether a state statute affects the relationships among "the core ERISA entities: beneficiaries, participants, administrators, employers, trustees and other fiduciaries," *see Gerosa,* 329 F.3d at 324, is

because the concern is about whether the *administration of benefits to beneficiaries* is affected. The majority ignores this distinction and treats all administrative burdens as weighing in favor of preemption.

The importance of separating any impact on the administration of benefits from general impact upon any administrative concern is clearly articulated in *Egelhoff v. Egelhoff ex rel. Breiner,* which involved a Washington state statute providing that "the designation of a spouse as the beneficiary of a nonprobate asset is revoked automatically upon divorce." 532 U.S. at 143. There, the Supreme Court stated that while "all state laws create some potential for a lack of uniformity," the concern was specifically whether "differing state regulations affect[ ] an ERISA plan's 'system for processing claims and paying benefits.' " *Id.* at 150 (quoting *Fort Halifax,* 482 U.S. at 10). The Court noted that the Washington statute at issue "interfere[d] with nationally uniform plan administration," as administrators could not "make payments simply by identifying the beneficiary specified by the plan documents" but instead had to "familiarize themselves with state statutes so that they c[ould] determine whether the named beneficiary's status has been 'revoked' by operation of law." *Id.* at 148-49. In clear contrast to *Egelhoff,* there is no argument here that the Vermont statute affects Liberty Mutual's "system for processing claims and paying benefits." *Id.* at 150 (internal quotation marks omitted).

It follows from these precedents that in order to show that the Vermont statute has a legally relevant

effect on ERISA plans, there must be evidence of a burden on the system for processing claims. No such evidence has been provided, and the majority points to none. The only possible conclusion on the record before us is that, other than through potential incidental costs, the Vermont statute does not hinder the national administration of employment benefit plans in any way. No new records need be kept, no distinction in benefits between Vermont and any other state need be made. This ends the inquiry.[3]

C. Reporting Requirements Upheld in *HMI* and *Burgio*

Using this same analysis, we twice concluded that ERISA did not preempt the reporting requirements in New York's prevailing wage law. *See HMI,* 266 F.3d 142; *Burgio,* 107 F.3d 1000. In both cases, the New York statute at issue required contractors and subcontractors to produce records showing their

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[3] Any support that the majority draws from *Standard Oil Co. v. Agsalud,* 633 F.2d 760, 763 (9th Cir. 1980), is misplaced. See Maj. Op. at 18-19. The Ninth Circuit opinion, which the Supreme Court summarily affirmed, does not even mention the reporting requirement in the Hawaii Prepaid Care Act. The Hawaii statute was found to be preempted because it directly and expressly regulated employers and the benefits they provided. The reporting requirement fell along with the rest of the statute *without* discussion. The fact that Congress did not amend ERISA to except reporting or disclosure requirements says nothing about whether a court asked to evaluate such requirements would find them to be preempted.

compliance with the prevailing wage rate and supplements. *See Burgio,* 107 F.3d at 1009; *HMI,* 266 F.3d at 151; N.Y. Lab. Law § 220. In *HMI,* we noted that although there were indirect effects on ERISA plans, such as "eliminating incentives for them to pool supplement contributions," the state's inquiry did not "mandat[e] a particular benefit structure for ERISA plans," "require employers or ERISA plans to provide specific benefits," or delve into the internal allocations of benefits within the plan. 266 F.3d at 150-51; *see also Burgio,* 107 F.3d at 1009 (finding no preemption where law did not "regulate . . . the terms and conditions of employee benefit plans", "prescribe [ ] . . . the type and amount of an employer's contribution to a plan", or the "nature and amount of the benefits provided"). Rather, we said that "information such as a list of plan participants, payroll lists, the amount of an employer's contributions and the names of people for whom the employer made contributions are appropriate areas of inquiry" for the state. *HMI,* 266 F.3d at 151. Both opinions make clear that a state may properly seek information from ERISA plans for its own purposes without triggering preemption so long as the request for information "creates no impediment to an employer's adoption of a uniform benefit administration scheme," *Burgio,* 107 F.3d at 1009. As discussed above, the Vermont statute creates no such impediment, and therefore survives under the same analysis.

The majority attempts to distinguish these cases based on the manner in which Vermont asks to be

provided information. But the fact that a particular format is required, without more, is meaningless. The record contains no evidence that the burden of providing data to Vermont (and other states which may ask for it) would keep plans from administering their benefits uniformly and therefore trigger ERISA preemption. Likewise, the majority's statement that the reporting requirement is "time-consuming and risky" (Maj. Op. at 26) – even if considered relevant under our precedent – is nothing more than pure speculation. There is no evidence to support such a finding.

CONCLUSION

Returning, then, to the language that must guide our inquiry, our decision depends on the objectives of the ERISA statute and the effect of the state law on ERISA plans. Although Congress intended to establish the regulation of employee benefit plans as an exclusively federal concern, it did not intend for health care to become the exclusive purview of the Federal Government. Rather, it anticipated that the States would continue to be involved in providing health care services to their citizens.

Liberty Mutual fails to overcome the presumption against preemption. The Vermont statute regulates health care within that state, while imposing a purely clerical burden on ERISA plans. I acknowledge that because Vermont may not be the only state with this type of law, plans governed by ERISA may need to provide their records in different formats. But our

case law does not support a finding that this warrants preemption. Indeed, it says uniformly that an economic burden imposed by a statute of general applicability, which does not affect the benefits that beneficiaries receive or how they receive them, is permissible.

Because the Vermont statute does not have an impermissible "connection with" ERISA plans, I respectfully dissent.

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

LIBERTY MUTUAL INSURANCE COMPANY,	:	
Plaintiff,	:	
v.	:	
STEPHEN W. KIMBELL, in his capacity as the Vermont Commissioner of Banking, Insurance, Securities and Health Care Administration,	:	Case No. 2:11-cv-204
Defendant.	:	

OPINION and ORDER

(Filed Nov. 9, 2012)

Plaintiff Liberty Mutual Insurance Company ("Liberty Mutual") seeks a declaration that Section 502(a) of the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1132(a), preempts Vermont's statute and regulation requiring it to provide information for the State's health care database, *see* Vt. Stat. Ann. tit. 18, § 9410 (2000 & Supp. 2011); Reg. H-2008-01, and to enjoin the enforcement of a subpoena directing the production of eligibility, medical claims and pharmacy claims files. Defendant Stephen W. Kimbell, in his official capacity as Commissioner of the Vermont Department of Banking,

Insurance, Securities and Health Care Administration ("BISHCA" or "Department"),[1] moved to dismiss the complaint for lack of standing and for failure to state a claim upon which relief can be granted. *See* Fed. R. Civ. P. 12(b)(1), 12(b)(6). Liberty Mutual moved for summary judgment. *See* Fed. R. Civ. P. 56(a). At oral argument on the motions, with the parties' concurrence, the Court converted the Department's Rule 12(b)(6) motion to one for summary judgment under Rule 56(a), in order to consider materials submitted outside the pleadings. *See* Fed. R. Civ. P. 12(d). For the reasons that follow, the Court concludes that Liberty Mutual has standing to bring this suit for declaratory and injunctive relief, but that the Department's motion for summary judgment is granted because ERISA does not preempt section 9410. Accordingly, the Department's Motion to Dismiss, ECF No. 15, is **granted in part and denied in part**. The motion is denied with respect to standing and granted with respect to ERISA preemption. Liberty Mutual's Motion for Summary Judgment, ECF No. 35, is **denied**. Liberty Mutual's Motion for Leave to Respond to Defendant's Notice of Supplemental Authority, ECF No. 52, is **granted**.

[1] BISHCA has been renamed, and is now the Department of Financial Regulation ("DFR").

Background[2]

Liberty Mutual is an insurance company organized under the laws of the Commonwealth of Massachusetts. It is a wholly owned subsidiary of Liberty Mutual Group Inc. Liberty Mutual has employees and offices in Vermont and conducts business within the state.

Liberty Mutual established the Liberty Mutual Medical Plan ("Plan") for the benefit of company employees. As of June 30, 2011, the Plan provided medical benefits to 84,711 persons throughout the United States, including 32,933 employees of Liberty Mutual Group, Inc. and its subsidiaries, plus employees' families and company retirees. As of that date, 137 plan participants or beneficiaries resided in Vermont.

As an employee welfare benefit plan, the Plan is governed by ERISA. Liberty Mutual is the "named fiduciary" and "plan administrator" of the Plan within the meaning of Section 3 of ERISA, 29 U.S.C. § 1002. The Plan is self-funded, or self-insured, meaning that Liberty Mutual Group, Inc. pays all benefits provided under the Plan from its own general assets. The Plan contracts with Blue Cross Blue Shield of Massachusetts, Inc. ("BCBSMA") as the third-party administrator ("TPA") of the Plan. As such, BCBSMA processes medical claims for Plan participants, receives participants'

[2] The facts set forth in this section are undisputed.

confidential medical records and generates claims data. The Administrative Services Agreement ("Agreement") between BCBSMA and Liberty Mutual provides that any information Liberty Mutual makes available must be used solely for the purpose of administering BCBSMA's health care plans, and that its auditors must have procedures in place to guard against unauthorized disclosure of health care information. *See* Agreement §§ 5, 6; ECF No. 22-4.

In Liberty Mutual's summary plan description ("SPD"), provided to participants, Liberty Mutual informs participants that information they provide in connection with screening for risk factors will be kept strictly confidential, and that if they participate in genetic testing the test is confidential. *See* SPD "Well-Baby Programs" at B-28, "Personalized Medicine Program" at B-46; ECF No. 22-5.

Liberty Mutual's Plan specifies that it "has been established for the exclusive benefit of Participants. . . ." *See* Plan § 9.1; ECF No. 22-2. It also provides that the Plan "shall comply with all other state and federal law to the extent not preempted by ERISA and to the extent such laws require compliance by the Plan." *Id.* § 9.9.

Liberty Mutual's Plan is subject to federal reporting and disclosure requirements set forth in ERISA Sections 101 through 110 and associated regulations. *See* 29 U.S.C. §§ 1021-1031; 29 C.F.R. §§ 2520.101-1 to 2520.107-1. In addition, Section 513 of ERISA authorizes the Secretary of Labor to "undertake

research and surveys and in connection therewith to collect, compile, analyze and publish data, information, and statistics relating to employee benefit plans. . . .” 29 U.S.C. § 1143(a).

Vermont has enacted legislation to create a unified health care database. *See* Vt. Stat. Ann. tit. 18, § 9410 (2000 & Supp. 2011). The database, established and maintained by the Department, is designed to enable the Department to determine the capacity of existing resources, identify health care needs, evaluate effectiveness, compare costs, provide information to consumers and purchasers of health care, and improve the quality and affordability of patient health care and health care coverage. *See* § 9410(a)(1)(A)-(F).

Section 9410 requires “health insurers,” which includes “any . . . entity with claims data . . . and other information relating to health care provided to Vermont resident[s],” § 9410(j)(1)(B), to “file reports, data, schedules, statistics, or other information determined by [the Department] to be necessary to carry out the purposes of” the statute. § 9410(c). The statute mandates the adoption of rules to carry out its purposes, § 9410(a)(2)(D), and provides for administrative penalties for knowing and for willful failure to comply with the statute or rules. § 9410(g).

Pursuant to the statute, the Department promulgated Regulation H-2008-01 to implement the creation of the unified health care database. It states:

> The purpose of this rule is to set forth the requirements for the submission of health care claims data, member eligibility data, and other information relating to health care provided to Vermont residents . . . by health insurers,. . . . third party administrators, . . . and others to the [DFR] and conditions for the use and dissemination of such claims data, all as required by and consistent with the purposes of . . . § 9410.

Reg. H-2008-01, § 1. The Vermont Healthcare Claims Uniform Reporting and Evaluation System ("VHCURES") is the Department's system for the collection, management and reporting of this data. *See id.* § 3Ar.

The regulation tracks the statute in defining "health insurer" to include entities defined in § 9410(j)(1), including

> any third party administrator . . . and any entity . . . possessing claims data, eligibility data, provider files, and other information relating to health care provided to Vermont residents or by Vermont health care providers and facilities. The term may also include, to the extent permitted under federal law, any administrator of an insured, self-insured, or publicly funded health care benefit plan offered by public and private entities.

Id. § 3X.

The parties do not dispute that Liberty Mutual and BCBSMA fall within the regulation's definition of "health insurer."

The regulation requires health insurers to register with the Department, and to identify whether health care claims are being paid for members who are Vermont residents or for non-residents who are receiving covered services from Vermont health care providers or facilities. *See id.* § 4A. Health insurers must "regularly submit medical claims data, pharmacy claims data, member eligibility data, provider data, and other information relating to health care provided to Vermont residents and health care provided by Vermont health care providers and facilities to both Vermont residents and non-residents in specified electronic format." *Id.* § 4D. The regulation sets a threshold for "mandated reporters," those health insurers with two hundred or more enrolled or covered members. *Id.* § 3Ab. All other health insurers are considered "voluntary reporters." *Id.* § 3As. Voluntary reporters may, but are not required to, participate in VHCURES. *See id.* § 4E.

The statute and regulation include various measures designed to protect confidential material. *See* §§ 9410(a)(2)(D) ("The rules shall permit health insurers to use security measures designed to allow subscribers access to price and other information without disclosing trade secrets to individuals and entities who are not subscribers."); (e) ("Records or information protected by the provisions of the physician-patient privilege . . . or otherwise required by

law to be held confidential, shall be filed in manner that does not disclose the identity of the protected person."); (f) (The commissioner shall adopt a confidentiality code to ensure that information obtained under this section is handled in an ethical manner."); (g) ("[A]ny person who knowingly fails to comply with the confidentiality requirements of this section or confidentiality rules adopted pursuant to this section and uses, sells, or transfers the data or information for commercial advantage, pecuniary gain, personal gain, or malicious harm shall be subject to an administrative penalty of not more than $50,000.00 per violation."); (h)(2)(D) ("Notwithstanding [the Health Insurance Portability and Accountability Act ("HIPAA")] or any other provision of law, the comprehensive health care information system shall not publicly disclose any data that contains direct personal identifiers. . . ."); *see also* Reg. H-2008-01 §§ 5(A)(5) (setting forth code and encryption requirements); 7(A)(5) ("Files submitted shall not contain direct personal identifiers."); 8(A) (classifying data elements as "unrestricted" and available for general use and public release; "restricted" and available for limited approved research uses; or "unavailable").

Subject to these strictures and the requirements of HIPAA, the statute and regulation allow the Department to make the data it collects "available as a resource for insurers, employers, providers, purchasers of health care, and state agencies to continuously review health care utilization, expenditures, and performance in Vermont." § 9410(h)(3)(B).

On August 5, 2011, the Department issued a subpoena to BCBSMA seeking eligibility, medical claims and pharmacy claims files for certain months. Liberty Mutual instructed BCBSMA not to report the information for Plan participants and beneficiaries, and filed this action seeking declaratory and injunctive relief. BCBSMA has complied with the subpoena with the exception of providing the data collected on the Vermont participants in Liberty Mutual's Plan, and has indicated that it will comply fully with the subpoena absent injunctive relief from this Court. *See* Verified Compl. ¶ 39, ECF No. 1.

The subpoena served on BCBSMA states that

> [p]ursuant to 8 V.S.A. § 13(b), a person who fails or refuses to produce papers or records for examination before the Commissioner, upon properly being ordered to do so, may be assessed an administrative penalty of the Commissioner of not more that [sic] $2,000.00 for each day of noncompliance and proceeded against as provided in the Administrative Procedure Act, and that person's authority to do business may be suspended for not more than six months.

Subpoena, ECF No. 1-1.

Discussion

I. Standing

The Department challenges Liberty Mutual's Article III standing. Standing, a "threshold question

in every federal case, determin[es] the power of the court to entertain the suit." *Warth v. Seldin,* 422 U.S. 490, 498 (1975). The "irreducible constitutional minimum of standing" requires a plaintiff to show (1) that it has "suffered an injury in fact – an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical; [(2)] a causal connection between the injury and the conduct complained of; [and (3) that it is] likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560 (1992) (citations and internal quotation marks omitted); *accord Carver v. City of New York,* 621 F.3d 221, 225 (2d Cir. 2010).

Because Liberty Mutual's standing is challenged by a Rule 12(b)(1) motion to dismiss, the Court accepts as true all material allegations of the complaint, and construes the complaint in Liberty Mutual's favor. *Id.* The Court also accepts the sworn declaration of Mary Connolly, ECF No. 22-1, with its attached exhibits, including copies of the Plan, the Summary Plan Description, and the Administrative Services Agreement between Liberty Mutual and BCBSMA. *See Warth,* 422 U.S. at 501.

The Department contends that Liberty Mutual cannot establish the first or second elements of Article III standing: concrete injury or causal connection. The Department points out that the subpoena is directed toward BCBSMA, not Liberty Mutual, and that it does not seek data from Liberty Mutual.

Therefore, it reasons, Liberty Mutual can suffer no injury if BCBSMA complies with the subpoena. Liberty Mutual responds that it has standing because it is the Plan fiduciary, and providing the data to the Department, or allowing the data to be provided, could constitute a violation of its fiduciary duties. It also asserts that the Plan owns the data demanded by the Department. *See* Verified Compl. ¶ 35.

Liberty Mutual is the Plan Administrator, and has control over the operation and administration of the Plan. Plan §§ 7.1-7.2. It is a fiduciary with respect to the Plan, given that it "exercises . . . discretionary authority or discretionary control respecting management" of the Plan. 29 U.S.C. § 1002(21)(A); *see Fin. Insts. Ret. Fund v. Office of Thrift Supervision,* 964 F.2d 142, 148 (2d Cir. 1992). Either by virtue of its plan administrator responsibilities or its fiduciary responsibilities, it has the authority to direct BCBSMA to refuse to provide Plan data to the Department.

It is undisputed that, as a voluntary reporter, Liberty Mutual itself may not be compelled to provide data to VHCURES. BCBSMA however is a mandated reporter, and is subject to section 9410's reporting requirements with respect to Liberty Mutual's Plan's data along with the data it acquires from other sources. When a plaintiff's asserted injury arises from the allegedly unlawful regulation of a third party, the plaintiff must "adduce facts" showing that the third party will act in such a fashion "as to

produce causation and permit redressability of injury." *Lujan,* 504 U.S. at 562.

According to the terms of the contract between BCBSMA and Liberty Mutual, Liberty Mutual agrees to hold BCBSMA harmless for any financial charges that may result at any time arising from or in connection with its self-insured ERISA health benefit plan. Agreement § 2. Liberty Mutual will therefore be responsible for any civil penalties assessed against BCBSMA because of BCBSMA's refusal to comply with the subpoena. The Department does not indicate that it will forbear enforcement of the subpoena directed to BCBSMA, and there is no suggestion that the threat of civil penalties is remote or speculative.

The Department's issuance of a subpoena to BCBSMA leaves two options open to Liberty Mutual. Liberty Mutual may allow BCBSMA to comply with the subpoena, allegedly in violation of ERISA and Liberty Mutual's fiduciary and administrative responsibilities to the Plan. Or Liberty Mutual may demand that BCBSMA refuse to comply with the subpoena, in which case it must indemnify BCBSMA if BCBSMA incurs civil penalties for its refusal, or sue BCBSMA if BCBSMA complies with the subpoena. As long as Liberty Mutual employs a mandated reporter to process its claims, and the Department insists on requiring that mandated reporter to report data obtained from voluntary reporters, Liberty Mutual is subject to regulation through the Department's regulation of BCBSMA.

An injury-in-fact "must be actual or imminent to ensure that the court avoids deciding a purely hypothetical case in which the projected harm may ultimately fail to occur." *Baur v. Veneman,* 352 F.3d 625, 632 (2d Cir. 2003). "'One does not have to await the consummation of threatened injury to obtain preventive relief. If the injury is certainly impending, that is enough.'" *Babbitt v. United Farm Workers Nat'l Union,* 442 U.S. 289, 298 (1979) (quoting *Pennsylvania v. West Virginia,* 262 U.S. 553, 593 (1923)). Under the circumstances presented here, Liberty Mutual has adequately alleged injury-in-fact. *See Davis v. Fed. Election Comm'n,* 554 U.S. 724, 733 (2008) (holding that a candidate for Congressional seat had standing to challenge election law disclosure requirements due to an imminent threat that he would have to make disclosure or face enforcement action).

With respect to the second element of constitutional standing, a causal connection, there can be no serious dispute that the forced reporting of its Plan's data is "fairly traceable to the challenged action" of the Department. *Lujan,* 504 U.S. at 560. The Department argues that BCBSMA would be the cause of any alleged injury to Liberty Mutual should BCBSMA comply with the subpoena, and that Liberty Mutual's injury is therefore caused by the independent action of "a third party not before the court." Mot. to Dismiss 5 (citing *Lujan,* 504 U.S. at 560). The Department fails to acknowledge that BCBSMA would not be inflicting an alleged injury upon Liberty Mutual were it not for the Department's subpoena and threatened

enforcement. The Department's actions need not be "the very last step in the chain of causation," *Bennett v. Spear,* 520 U.S. 154, 169 (1997); it will suffice if Liberty Mutual's injury is produced by the Department's "coercive effect upon the action of someone else," *id.,* in this case BCBSMA.

The Department suggests – although it has not briefed the issue – that Liberty Mutual also cannot satisfy the redressability element of constitutional standing. Mot. to Dismiss 6. On the contrary, a favorable decision from this Court would allow Liberty Mutual to avoid providing its health care data to the Department, exactly the harm of which Liberty Mutual complains. *See Sprint Commc'ns Co., L.P. v. APCC Servs., Inc.,* 554 U.S. 269, 287 (2008) (reiterating that the redressability inquiry focuses on whether the particular injury alleged is likely to be redressed through the litigation).

Liberty Mutual has adequately alleged constitutional standing.

II. Preemption

Both parties seek summary judgment on the claim that ERISA preempts section 9410 and its accompanying regulation. Summary judgment is appropriate if the moving party "shows that there is no genuine dispute as to any material fact and [it] is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

> Under Rule 56[(a)] the moving party has the burden of showing the absence of any genuine issue of material fact. A fact is material when its resolution would affect the outcome of the suit under the governing law, and a dispute about a material fact is genuine if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.

Gen. Elec. Co. v. New York State Dep't of Labor, 936 F.3d 1448, 1452 (2d Cir. 1991) (citations and quotation marks omitted). "Where . . . there are cross-motions for summary judgment, each party's motion must be examined on its own merits, and in each case all reasonable inferences must be drawn against the party whose motion is under consideration." *Lumbermens Mut. Cas. Co. v. RGIS Inventory Specialists, LLC,* 628 F.3d 46, 51 (2d Cir. 2010) (quotation marks and citation omitted).

The parties do not dispute that ERISA regulates Liberty Mutual's Plan. *See N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.,* 514 U.S. 645, 656 (1995) ("ERISA's comprehensive regulation of employee welfare and pension benefit plans extends to those that provide 'medical, surgical, or hospital care or benefits' for plan participants or their beneficiaries 'through the purchase of insurance or otherwise.'") (quoting 29 U.S.C. § 1002(1)); *see also Boggs v. Boggs,* 520 U.S. 833, 839, 841 (1997) ("ERISA is designed to ensure the proper administration of pension and welfare plans. . . . All employee

benefit plans must conform to various reporting, disclosure, and fiduciary requirements.").

ERISA Section 514(a) provides that, subject to certain exceptions, the provisions of Title I and Title IV of ERISA "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" described in section 4(a) and not exempt under section 4(b) of ERISA. 29 U.S.C. § 1144(a). State law "includes all laws, decisions, rules, regulations or other State action having the effect of law." *Id.* § 1144(c)(1).

The Supreme Court originally gave this express preemption provision sweeping scope. In *Shaw v. Delta Air Lines, Inc.,* the Court stated "[t]he breadth of § 514(a)'s pre-emptive reach is apparent from that section's language." 463 U.S. 85, 96 (1983). It held that "[a] law 'relates to' an employee benefit plan, in the normal sense of the phrase, if it has a connection with or reference to such a plan." *Id.* at 96-97.

By the mid-1990's, however, the Court found ERISA's broad language "opaque," *De Buono v. NYSA-ILA Med. & Clinical Serv. Fund,* 520 U.S. 806, 809 (1997), and "unhelpful," *Travelers,* 514 U.S. at 656, remarking that "[i]f 'relate to' were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course, for really, universally, relations stop nowhere." *Id.* at 655; *accord Calif. Div. of Labor Standards Enforcement v. Dillingham Const., N.A., Inc.,* 519 U.S. 316, 335 (1997) (Scalia, J. concurring)

("since . . . everything is related to everything else", suggesting that applying "relate to" literally had failed).

In *Travelers,* the Court placed ERISA preemption on the same footing as its other preemption cases, beginning with the presumption that Congress does not intend to supplant state law, particularly in areas of traditional state regulation. 514 U.S. at 654-55. Nevertheless, the Court has continued to adhere to *Shaw*'s two-pronged test for determining whether a state law relates to an employee benefit plan: "A law 'relates to' an employee benefit plan . . . if it has a connection with or reference to such a plan." *Shaw,* 463 U.S. at 96-97. Because the meaning of "relate to" is open to interpretation, "sensible construction of ERISA . . . requires [a court to] measure these words in context." *UNUM Life Ins. Co. of Am. v. Ward,* 526 U.S. 358, 363 (1999). Thus in this Circuit courts, following *Travelers,* consider that "two kinds of state laws relate to ERISA for purposes of preemption: 'those that mandate employee benefit structures or their administration, and those that provide alternative enforcement mechanisms.'" *HMI Mech. Sys., Inc. v. McGowan,* 266 F.3d 142, 149 (2d Cir. 2001) (quoting *Burgio & Campofelice, Inc. v. N.Y. State Dep't of Labor,* 107 F.3d 1000, 1008 (2d Cir. 1997)).

A. The Presumption Against Preemption

"[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern."

Hillsborough County, Fla. v. Automated Med. Labs., Inc., 471 U.S. 707, 719 (1985); *accord Travelers,* 514 U.S. at 661-62; *see also Florida v. U.S. Dept. of Health & Human Servs.,* 648 F.3d 1235, 1305 (11th Cir. 2011) ("The health care industry . . . falls within the sphere of traditional state regulation."), *aff'd in part, rev'd in part sub nom. Nat'l Fed'n of Indep. Bus. v. Sebelius,* 132 S. Ct. 2566 (2012). Vermont's health care database was established to further the State's policy "to ensure that all residents have access to quality health services at costs that are affordable." Vt. Stat. Ann. tit. 18, § 9401(a). Among the specific duties that the database is designed to assist with are "comparing costs between various treatment settings and approaches" and "improving the quality and affordability of patient health care and health care coverage." §§ 9410(a)(1)(D), (F).

A statute that operates in the health care field will receive the benefit of the presumption against preemption, even if it does not directly regulate health care providers or services. For example, in 1997 the Supreme Court considered whether a New York statute that imposed a tax on gross receipts for patient services was preempted as applied to medical centers operated by ERISA plans. *DeBuono,* 520 U.S. at 809. The Court acknowledged that the law was a revenue-raising measure rather than a regulation of hospitals; nevertheless it applied the presumption against preemption because the statute "clearly operates in a field that has been traditionally occupied by the States." *Id.* at 814 (internal quotation

marks and citation omitted). The Court distinguished the statute at issue from types of state law that Congress intended ERISA to preempt: laws that forbid a method of calculating pension benefits, or require the provision of certain benefits; state-law causes of action in which the existence of a pension plan is a critical element; laws that expressly refer to ERISA or ERISA plans. *Id.* at 814-15. It observed that "[a]ny state . . . law[ ] that increases the cost of providing benefits to covered employees will have some effect on the administration of ERISA plans, but that simply cannot mean that every state law with such an effect is pre-empted by the federal statute," *id.* at 816, and held that New York could collect its tax. *Id.* at 809.

That Congress also regulates in the field of health care or health information technology, *see* HIPAA, Pub. L. No. 104-191, 110 Stat. 1936 (1996), for example, doesn't disturb the presumption against preemption for a state law that operates in the field of health care. Nevertheless, the presumption against preemption "can be overcome where . . . Congress has made clear its desire for pre-emption." *Egelhoff v. Egelhoff,* 532 U.S. 141, 151 (2001).

B. Reference to ERISA Plans

"Where a State's law acts immediately and exclusively upon ERISA plans, . . . or where the existence of ERISA plans is essential to the law's operation, . . . that 'reference' will result in pre-emption."

Dillingham, 519 U.S. at 325. "'State laws which are specifically designed to affect employee benefit plans are preempted.'" *Ingersoll-Rand Co. v. McClendon,* 498 U.S. 133, 140 (1990) (quoting *Mackey v. Lanier Collection Agency & Serv., Inc.,* 486 U.S. 825, 829 (1988)).

Liberty Mutual asserts that the regulation expressly mentions self-funded ERISA plans, and requires such plans to report their data.[3] That is certainly true. But "'[t]he Supreme Court has never found a statute to be preempted simply because the word ERISA (or its equivalent) appears in the text.'" *Romney v. Lin,* 94 F.3d 74, 79 (2d Cir. 1996) (quoting *NYS Health Maint. Org. Conference v. Curiale,* 64 F.3d 794, 800 (2d Cir. 1995)); *accord Hattem v. Schwarzenegger,* 449 F.3d 423, 432 (2d Cir. 2006) ("While singling out ERISA plans for special treatment is considered a 'reference,' simply mentioning the word 'ERISA' is not.").[4]

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[3] Section 3X includes in its definition of "health insurer," "to the extent permitted under federal law, any administrator of an insured, self-insured, or publicly funded health care benefit plan offered by public and private entities." Reg. H-2008-01, § 3X. Health insurers, with the exception of voluntary reporters, must submit medical claims data, pharmacy claims data, member eligibility data, provider data, and other information relating to health care. . . ." *Id.* § 4D, E.

[4] The contrary is also true of course. A statute may "refer" to ERISA plans and therefore be preempted without actually using the phrase. *See Romney,* 94 F.3d at 78 (citing cases).

In *Curiale,* a Second Circuit panel held that a state regulation that established health insurance pools to equalize the risk of high-cost claims or persons did not refer to an ERISA plan. Even though the regulation "implicate [d]" ERISA plans, its "allusion" to ERISA was "not tantamount to a reference because the regulation [could] be applied without guidance from or interference with an ERISA plan." *Id.* at 801. The calculation of an insurer's pool contributions or reimbursements was unaffected by the presence or absence of an ERISA plan in the pool, because the contributions or reimbursements were based upon the insurer's membership, not on the benefits provided to the members. And the regulation did not require any changes to the contents of the benefits package. *Id.*

In a challenge to Maine's Unfair Prescription Drug Practices Act, a First Circuit panel found no ERISA preemption. *See Pharm. Care Mgmt. Ass'n v. Rowe,* 429 F.3d 294, 299 (1st Cir. 2005), *cert. denied,* 547 U.S. 1179 (2006). Relying upon *Dillingham,* and its own precedents, it emphasized that the existence of ERISA plans was not essential to the operation of the statute, and that the statute applies to a broad spectrum of health care institutions and health benefit providers. *Id.* at 303. "'[A] state law that applies to a wide variety of situations, including an appreciable number that have no specific linkage to ERISA plans, constitutes a law of general application for purposes of 29 U.S.C. § 1144.'" *Id.* at 304 (quoting

Carpenters Local Union No. 26 v. United States Fid. & Guar. Co., 215 F.3d 136, 144-45 (1st Cir. 2000)).

Vermont's statute and regulation do not act immediately and exclusively upon ERISA plans, nor is the existence of ERISA plans essential to their operation. Self-insured plans and their TPAs are only two of several entities that the statute and regulation cover. The Department affirms that VHCURES data includes information provided by BCBSMA from other self-funded plans, as well as from members not affiliated with an ERISA plan. *See* Aff. of Dian Kahn ¶¶ 5-6, ECF No. 48-1. VHCURES also requires data from hospitals, health insurance companies, managed care organizations and pharmacy benefit managers among others. *See* § 9410(c); Reg. H-2008-01 § 3X.

Vermont's statute and regulation, which "'function[ ] irrespective of . . . the existence of an ERISA plan,'" *Dillingham,* 519 U.S. at 328 (quoting *Ingersoll-Rand Co.,* 498 U.S. at 139), do not make reference to ERISA plans as that term is understood by the United States Supreme Court and the Second Circuit. *See, e.g., Dillingham,* 519 U.S. at 328; *Hattem,* 449 F.3d at 435.

C. Connection with ERISA Plans

To determine whether a state law has a connection with ERISA plans, the Court "look[s] to the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive," *Travelers,* 514 U.S. at 656, "as well as

to the nature of the effect of the state law on ERISA plans." *Dillingham,* 519 U.S. at 325. The Supreme Court "ha[s] cautioned against an uncritical literalism that would make pre-emption turn on infinite connections," *Egelhoff,* 532 U.S. at 147 (internal quotation marks and citation omitted); yet if a statute "implicates an area of core ERISA concern," it will have an impermissible connection with ERISA plans. *Id.*

In *Gerosa v. Savasta & Co.,* 329 F.3d 317, 324 (2d Cir. 2003), the appeals court surveyed lower court opinions attempting to apply the Supreme Court's ERISA preemption principles, and identified "several clear trends." One, courts' preemption analyses have focused "on the core ERISA entities: beneficiaries, participants, administrators, employers, trustees and other fiduciaries, and the plan itself. Courts are reluctant to find that Congress intended to preempt state laws that do not affect the relationships among these groups." *Id.* Two, "state laws that would tend to control or supersede central ERISA functions – such as state laws affecting the determination of eligibility for benefits, amounts of benefits, or means of securing unpaid benefits – have typically been found to be preempted." *Id.*; *accord Stevenson v. Bank of N.Y. Co.,* 609 F.3d 56, 59 (2d Cir. 2010); *see also Pharm. Care Mgmt. Ass'n v. Dist. of Columbia,* 613 F.3d 179, 184 (D.C. Cir. 2010) ("The administration of employee benefits clearly is an area of core ERISA concern, [and o]ne of the principal goals of ERISA is to enable employers to establish a uniform administrative

scheme, which provides a set of standard procedures to guide processing of claims and disbursement of benefits.") (internal quotation marks and citation omitted); *Gen. Elec. Co.,* 891 F.2d at 29 (A state law has a connection with ERISA plans where it "prescribes either the type and amount of an employer's contributions to a plan, the rules and regulations under which the plan operates, or the nature and amount of the benefits provided thereunder.") (citations omitted); *Aetna Life Ins. Co. v. Borges,* 869 F.2d 142, 146-47 (2d Cir. 1989) ("What triggers ERISA preemption is not just any indirect effect on administrative procedures but rather an effect on the primary administrative functions of benefit plans, such as determining an employee's eligibility for a benefit and the amount of that benefit."); *accord Howard v. Gleason Corp.,* 901 F.2d 1154, 1157 (2d Cir. 1990).

In *Hattem,* the appeals court took a close look at *Travelers,* noting that "preemption is not called for 'if the state law has only a tenuous, remote, or peripheral connection with covered plans, as is the case with many laws of general applicability.'" 449 F.3d at 429 (quoting *Travelers,* 514 U.S. at 661). An indirect economic effect on choices that a plan administrator must make is insufficient; "rather, the law must actually dictate which choices *must* be made." *Id.* A state law's indirect economic effect may, however, be so "acute" "'as to force an ERISA plan to adopt a certain scheme,' which might result in preemption." *Id.* (quoting *Travelers,* 514 U.S. at 668).

Hattem also discussed the Supreme Court's decision in *Egelhoff,* in which the Court found that a state law did have an impermissible connection with an employee benefit plan. 532 U.S. at 147. The Washington statute at issue automatically revoked upon divorce an individual's beneficiary designation on any nonprobate asset. This law "interfered with a nationally uniform plan administration, the creation of which was another goal of ERISA." 449 F.3d at 430 (citing *Egelhoff,* 532 U.S. at 148-50). Were a similar law adopted in every state, a plan administrator would have to research every state's law each time it needed to pay the beneficiary of a plan participant. *Id.*

Vermont's statute and regulation does not require any particular health plan or benefit structure, or specific benefits or enforcement mechanism. It does not alter the procedures by which Liberty Mutual processes claims and disburses benefits. There is no evidence that the law affects the relationships among core ERISA entities or creates an economic effect so acute as to dictate certain administrative choices.[5]

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[5] Vermont's law does not in fact require Liberty Mutual to do anything at all. BCBSMA bears the burden of compliance, if there is one. There is no evidence that BCBSMA is laboring under any sort of burden. Although Liberty Mutual has argued with fervor that the reporting obligations are "onerous," "staggering," "extensive and arcane, and a distraction from plan administration," Mem. in Supp. of Mot. for Summ. J. 17, ECF No. 35-1, citing the length and detail of the regulation itself and the Department's reference manual for companies subject to the

(Continued on following page)

Nevertheless, Liberty Mutual stresses the Supreme Court's commentary that the purpose of ERISA's preemption provision was "to ensure that plans and plan sponsors would be subject to a uniform body of benefits law; the goal was to minimize the administrative and financial burden of complying with conflicting directives among States or between States and the Federal Government." *Ingersoll-Rand,* 498 U.S. at 143; *accord Burgio & Campofelice, Inc. v. New York State Dep't of Labor,* 107 F.3d 1000, 1007-08 (2d Cir. 1997); *see also Travelers,* 514 U.S. at 657 (describing the objective of ERISA preemption "as being to 'eliminate[e] [sic] the threat of conflicting and inconsistent State and local regulation.'" (quoting Representative John Dent, a sponsor of the legislation)). The Supreme Court has generalized on more than one occasion that Section 514(a) preempts "state laws dealing with the subject matters covered by ERISA," including reporting and disclosure. *Shaw,* 463 U.S. at 98; *accord Travelers,* 514 U.S. at 661; *FMC Corp. v. Holliday,* 498 U.S. 52, 58-59 (1990). Thus, in Liberty Mutual's view ERISA preempts any state law that imposes a reporting requirement on an ERISA plan, regardless of the purpose for the data, the type of data required, or the law's effect if any on

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regulation, it has not submitted any information about any actual burden suffered by itself or BCBSMA in producing this information. BCBSMA apparently provides the data without protest on behalf of other self-funded plans. *See* Kahn Aff. ¶¶ 5-6.

core ERISA entities, their functions or their relationships. Liberty Mutual draws support for this position from ERISA's legislative history and the fate of Hawaii's Prepaid Health Care Act, passed in 1974.[6]

Upon examining ERISA's legislative history, the Supreme Court stated that the scope of ERISA's preemption provision is "as broad as its language." *Shaw,* 463 U.S. at 98; *accord FMC Corp.,* 498 U.S. at 59. Yet it also warned against an "uncritical literalism," *Egelhoff,* 532 U.S. at 147, and stressed that parties' contentions about the scope of ERISA preemption must be viewed in context. *See Boggs v. Boggs,* 520 U.S. at 845. Thus the Court has consistently emphasized that "the principal object of the statute is to protect plan participants and beneficiaries." *Id.*; *see also Dillingham,* 519 U.S. at 326-27 ("'In enacting ERISA, Congress' primary concern was with the mismanagement of funds accumulated to finance employee benefits and the failure to pay employees benefits from accumulated funds. *To that end,* it

[6] Also in 1974, the year ERISA was enacted with its express preemption clause, Congress enacted the National Health Planning and Resources Development Act of 1974 ("NHPRDA"), Pub. L. No. 93-641, 88 Stat. 2225. Among other things, this law required states to create health planning agencies which would, among other things, be responsible for the gathering and analysis of data relevant to the costs of medical services. *See Travelers,* 514 U.S. at 665. Following Liberty Mutual's reasoning that any reporting requirement that affects an ERISA plan is preempted, Congress would have precluded the states' gathering of cost information from ERISA plans even as Congress was authorizing such activity with the NHPRDA.

established extensive reporting, disclosure, and fiduciary duty requirements to insure against the possibility that the employee's expectation of the benefit would be defeated through poor management by the plan administrator.'") (quoting *Massachusetts v. Morash,* 490 U.S. 107, 115 (1989) (emphasis supplied)); *Travelers,* 514 U.S. at 651 (ERISA "protect[s] plan participants and their beneficiaries by . . . control[ling] the administration of benefit plans . . . as by imposing reporting and disclosure mandates. . . .").

If "[t]he focus of [ERISA] . . . is on the administrative integrity of benefit plans," *Fort Halifax Packing Co. v. Coyne,* 482 U.S. 1, 15 (1987), it is to assure uniformity of regulation with respect to the *activities* and *operations* of such plans. *Id.* at 15-16 (citing and quoting from the legislative history). The appropriate question therefore is not the uncritically literal one of whether Vermont's health care database law imposes a reporting requirement on the TPA of an ERISA plan. It is rather a more contextual one: whether a state data reporting requirement dictates or disrupts the activities or operations of an ERISA plan, or compromises the administrative integrity of an ERISA plan, or in some way creates state oversight of the administration of an ERISA plan.

For example, the case cited by Liberty Mutual as a paradigm of ERISA preemption was a challenge to Hawaii's Prepaid Health Care Act. The Act included reporting and disclosure requirements along with its imperative to private employers to establish health care benefit plans. In *Standard Oil Co. of California*

v. Agsalud, 633 F.2d 760, 763 (9th Cir. 1980), the Ninth Circuit struck down the statute. Its reporting, disclosure and fiduciary requirements fell, without discussion, along with the benefits requirement. *Id.* at 765-66, *aff'd mem.,* 454 U.S. 801 (1981).[7]

The Hawaii statute was preempted because it required the establishment of ERISA plans or dictated the terms of existing plans, and gave the state oversight over ERISA plans' operations. *See Golden Gate Restaurant Ass'n v. City & County of San Francisco,* 546 F.3d 639, 655 (9th Cir. 2008) (describing *Agsalud* as holding that "the Hawaii statute was preempted because it required employers to have health plans, and it dictated the specific benefits employers were to provide through those plans"), *cert. denied,* 130 S. Ct. 3497 (2010); *see also Fort Halifax,* 482 U.S. at 12-13 (describing the Hawaii statute as preempted because it required the establishment of a health care plan or required existing plans to pay certain benefits).

Vermont's statute and regulation, which have nothing to do with mandating employee benefit plans or benefits and do not attempt any sort of oversight over compliance, bear no resemblance to Hawaii's

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[7] In 1983 Congress amended ERISA to specifically exempt from preemption certain provisions of the Hawaii statute that predated ERISA. *See* 29 U.S.C. § 1144(b)(5). The exempted provisions did not include the reporting or disclosure requirements, which remained preempted by the *Agsalud* ruling. *See Fort Halifax,* 482 U.S. at 13 n.7.

Prepaid Health Care Act, and "create[ ] no impediment to an employer's adoption of a uniform benefit administration scheme." *Id.* at 14 (holding that a Maine statute requiring a one-time severance payment to employees in the event of a plant closing was not preempted because it did not mandate a benefit plan or require the establishment of a scheme to administer benefits, or change or alter its ability to operate its plan).

The Second Circuit Court of Appeals' opinion in *HMI Mechanical Systems* further illustrates the distinction between a state law that requires ERISA plans to provide specific benefits or follow certain eligibility criteria and a state law that seeks information held by plans. New York law requires businesses who perform public work projects to pay their employees the locally prevailing wage amount, which encompasses not only cash wages but non-cash benefits such as health, retirement and disability benefits. A business may comply with the law by contributing to an ERISA plan on behalf of its employees. HMI, as a business subject to the law, refused to comply with the state's demands for information about HMI's contributions to its ERISA plans. It sought a declaration that ERISA preempted the state's investigation into its allocation of benefits, contending that the state sought to regulate the administration of an ERISA plan. The district and appeals courts disagreed, concluding that the state was not mandating a particular benefit structure or requiring particular contributions. 266 F.3d at 151. It held only that the

state could not delve into the internal allocations of benefits within the plan. *Id.* at 151-52.

The Department's efforts to enforce its health care database statute and regulation do not seek to regulate the administration of Liberty Mutual's Plan, or its allocation of benefits. Providing the information requested may create some degree of administrative burden for the TPA and by extension Liberty Mutual; such an effect, peripheral to the core ERISA functions and relationships, does not warrant preemption.

Conclusion

Section 9410 and its accompanying regulation is a law of general applicability concerning an area of traditional state police power. The law applies to a broad range of entities, including health care providers, health care facilities and health insurers. § 9410(c). It is not directed at any particular plans, or types of plans, or employee benefit plans in general. The State's intention is to improve the administration of health care services, and it has determined that it is in need of better health care data to ensure the delivery of quality health services at an affordable cost. Plans such as Liberty Mutual's have data that can assist the achievement of that goal. Compliance with the reporting requirements of H-2008-1 may have some indirect effect on health benefit plans, but that effect is so peripheral that the regulation cannot be considered an attempt to interfere with the administration or structure of a welfare benefit plan. *See*

De Buono, 520 U.S. at 815-16 (concluding that a state statute that imposes some administrative burden on an ERISA plan is not automatically preempted).

"[I]n the field of health care, a subject of traditional state regulation, there is no ERISA preemption without clear manifestation of congressional purpose." *Pegram v. Herdrich,* 530 U.S. 211, 237 (2000). Liberty Mutual has not overcome the presumption against preemption. The law does not make reference to ERISA plans, as that term has been construed in the case law, and makes no attempt to control, supersede or interfere with the operation of an ERISA plan. In short, because the law's reporting requirement has no effect whatsoever on the core relationships that ERISA was designed to protect – those between participants, beneficiaries, administrators and employers – and no effect whatsoever on the core ERISA functions – such as processing claims or disbursing benefits – "it poses no danger of undermining the uniformity of the administration of benefits that is ERISA's key concern." *Stevenson,* 609 F.3d at 61. "[P]reemption of [Vermont's] law would not serve the purpose for which ERISA's preemption provision was enacted." *Fort Halifax,* 482 U.S. at 14-15. Liberty Mutual's motion for summary judgment is therefore **denied**. The Department's motion to dismiss is **denied** with respect to standing and **granted** with respect to preemption.

CASE CLOSED.

Dated at Burlington, in the District of Vermont, this 9th day of November, 2012.

/s/ William K. Sessions III
William K. Sessions III
District Court Judge

UNITED STATES COURT OF APPEALS
FOR THE
SECOND CIRCUIT

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 16th day of May, two thousand fourteen,

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Liberty Mutual
Insurance Company,

Plaintiff-Appellant,

v.

Susan L. Donegan, in her capacity as the Commissioner of the Vermont Department of Financial Regulation,

Defendant-Appellee.

ORDER

Docket No: 12-4881

Appellee Susan L. Donegan filed a petition for panel rehearing, or, in the alternative, for rehearing *en banc*. The panel that determined the appeal has considered the request for panel rehearing, and the active members of the Court have considered the request for rehearing *en banc*.

IT IS HEREBY ORDERED that the petition is denied.

FOR THE COURT:
Catherine O'Hagan Wolfe,
Clerk

[SEAL]

/s/ Catherine O'Hagan Wolfe

United States Code
Title 29. Labor
Chapter 18. Employee Retirement
Income Security Program

§ 1144. Other laws

(a) Supersedure; effective date

Except as provided in subsection (b) of this section, the provisions of this subchapter and subchapter III of this chapter shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described in section 1003(a) of this title and not exempt under section 1003(b) of this title. This section shall take effect on January 1, 1975.

(b) Construction and application

(1) This section shall not apply with respect to any cause of action which arose, or any act or omission which occurred, before January 1, 1975.

(2)(A) Except as provided in subparagraph (B), nothing in this subchapter shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities.

(B) Neither an employee benefit plan described in section 1003(a) of this title, which is not exempt under section 1003(b) of this title (other than a plan established primarily for the purpose of providing death benefits), nor any trust established under such a plan, shall be deemed to be an insurance company

or other insurer, bank, trust company, or investment company or to be engaged in the business of insurance or banking for purposes of any law of any State purporting to regulate insurance companies, insurance contracts, banks, trust companies, or investment companies.

(3) Nothing in this section shall be construed to prohibit use by the Secretary of services or facilities of a State agency as permitted under section 1136 of this title.

(4) Subsection (a) of this section shall not apply to any generally applicable criminal law of a State.

(5)(A) Except as provided in subparagraph (B), subsection (a) of this section shall not apply to the Hawaii Prepaid Health Care Act (Haw.Rev.Stat. §§ 393-1 through 393-51).

(B) Nothing in subparagraph (A) shall be construed to exempt from subsection (a) of this section –

(i) any State tax law relating to employee benefit plans, or

(ii) any amendment of the Hawaii Prepaid Health Care Act enacted after September 2, 1974, to the extent it provides for more than the effective administration of such Act as in effect on such date.

(C) Notwithstanding subparagraph (A), parts 1 and 4 of this subtitle, and the preceding sections of this part to the extent they govern matters which are governed by the provisions of such parts 1 and 4, shall

supersede the Hawaii Prepaid Health Care Act (as in effect on or after January 14, 1983), but the Secretary may enter into cooperative arrangements under this paragraph and section 1136 of this title with officials of the State of Hawaii to assist them in effectuating the policies of provisions of such Act which are superseded by such parts 1 and 4 and the preceding sections of this part.

(6)(A) Notwithstanding any other provision of this section –

(i) in the case of an employee welfare benefit plan which is a multiple employer welfare arrangement and is fully insured (or which is a multiple employer welfare arrangement subject to an exemption under subparagraph (B)), any law of any State which regulates insurance may apply to such arrangement to the extent that such law provides –

(I) standards, requiring the maintenance of specified levels of reserves and specified levels of contributions, which any such plan, or any trust established under such a plan, must meet in order to be considered under such law able to pay benefits in full when due, and

(II) provisions to enforce such standards, and

(ii) in the case of any other employee welfare benefit plan which is a multiple employer welfare arrangement, in addition to this subchapter, any law of any State which regulates insurance may

apply to the extent not inconsistent with the preceding sections of this subchapter.

(B) The Secretary may, under regulations which may be prescribed by the Secretary, exempt from subparagraph (A)(ii), individually or by class, multiple employer welfare arrangements which are not fully insured. Any such exemption may be granted with respect to any arrangement or class of arrangements only if such arrangement or each arrangement which is a member of such class meets the requirements of section 1002(1) and section 1003 of this title necessary to be considered an employee welfare benefit plan to which this subchapter applies.

(C) Nothing in subparagraph (A) shall affect the manner or extent to which the provisions of this subchapter apply to an employee welfare benefit plan which is not a multiple employer welfare arrangement and which is a plan, fund, or program participating in, subscribing to, or otherwise using a multiple employer welfare arrangement to fund or administer benefits to such plan's participants and beneficiaries.

(D) For purposes of this paragraph, a multiple employer welfare arrangement shall be considered fully insured only if the terms of the arrangement provide for benefits the amount of all of which the Secretary determines are guaranteed under a contract, or policy of insurance, issued by an insurance company, insurance service, or insurance organization, qualified to conduct business in a State.

(7) Subsection (a) of this section shall not apply to qualified domestic relations orders (within the meaning of section 1056(d)(3)(B)(i) of this title), qualified medical child support orders (within the meaning of section 1169(a)(2)(A) of this title), and the provisions of law referred to in section 1169(a)(2)(B)(ii) of this title to the extent they apply to qualified medical child support orders.

(8) Subsection (a) of this section shall not be construed to preclude any State cause of action –

(A) with respect to which the State exercises its acquired rights under section 1169(b)(3) of this title with respect to a group health plan (as defined in section 1167(1) of this title), or

(B) for recoupment of payment with respect to items or services pursuant to a State plan for medical assistance approved under title XIX of the Social Security Act [42 U.S.C.A. § 1396 et seq.] which would not have been payable if such acquired rights had been executed before payment with respect to such items or services by the group health plan.

(9) For additional provisions relating to group health plans, see section 1191 of this title.

(c) Definitions

For purposes of this section:

(1) The term "State law" includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the

United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

(2) The term "State" includes a State, any political subdivisions thereof, or any agency or instrumentality of either, which purports to regulate, directly or indirectly, the terms and conditions of employee benefit plans covered by this subchapter.

(d) Alteration, amendment, modification, invalidation, impairment, or supersedure of any law of the United States prohibited

Nothing in this subchapter shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States (except as provided in sections 1031 and 1137(b) of this title) or any rule or regulation issued under any such law.

(e)(1) Notwithstanding any other provision of this section, this subchapter shall supersede any law of a State which would directly or indirectly prohibit or restrict the inclusion in any plan of an automatic contribution arrangement. The Secretary may prescribe regulations which would establish minimum standards that such an arrangement would be required to satisfy in order for this subsection to apply in the case of such arrangement.

(2) For purposes of this subsection, the term "automatic contribution arrangement" means an arrangement –

(A) under which a participant may elect to have the plan sponsor make payments as contributions under the plan on behalf of the participant, or to the participant directly in cash,

(B) under which a participant is treated as having elected to have the plan sponsor make such contributions in an amount equal to a uniform percentage of compensation provided under the plan until the participant specifically elects not to have such contributions made (or specifically elects to have such contributions made at a different percentage), and

(C) under which such contributions are invested in accordance with regulations prescribed by the Secretary under section 1104(c)(5) of this title.

(3)(A) The plan administrator of an automatic contribution arrangement shall, within a reasonable period before such plan year, provide to each participant to whom the arrangement applies for such plan year notice of the participant's rights and obligations under the arrangement which –

(i) is sufficiently accurate and comprehensive to apprise the participant of such rights and obligations, and

(ii) is written in a manner calculated to be understood by the average participant to whom the arrangement applies.

(B) A notice shall not be treated as meeting the requirements of subparagraph (a) with respect to a participant unless –

(i) the notice includes an explanation of the participant's right under the arrangement not to have elective contributions made on the participant's behalf (or to elect to have such contributions made at a different percentage),

(ii) the participant has a reasonable period of time, after receipt of the notice described in clause (i) and before the first elective contribution is made, to make such election, and

(iii) the notice explains how contributions made under the arrangement will be invested in the absence of any investment election by the participant.

Vermont Statutes Annotated
Title Eighteen. Health
Chapter 221. Health Care Administration
Subchapter 1. Health Information Technology
§ 9401. Policy

(a) It is the policy of the state of Vermont that health care is a public good for all Vermonters and to ensure that all residents have access to quality health services at costs that are affordable. To achieve this policy, it is necessary that the state ensure the quality of health care services provided in Vermont and, until health care systems are successful in controlling their costs and resources, to oversee cost containment.

(b) It is further the policy of the state of Vermont that the health care system should:

(1) Maintain and improve the quality of health care services offered to Vermonters.

(2) Utilize planning, market, and other mechanisms that contain or reduce increases in the cost of delivering services so that health care costs do not consume a disproportionate share of Vermonters' incomes or the moneys available for other services required to insure the health, safety, and welfare of Vermonters.

(3) Encourage regional and local participation in decisions about health care delivery, financing, and provider supply.

(4) Utilize planning, market, and other mechanisms that will achieve rational allocation of health care resources in the state.

(5) Facilitate universal access to preventive and medically necessary health care.

(6) Support efforts to integrate mental health and substance abuse services with overall medical care.

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§ 9410. Health care database

(a)(1) The Board shall establish and maintain a unified health care database to enable the Commissioner and the Board to carry out their duties under this chapter, chapter 220 of this title, and Title 8, including:

(A) determining the capacity and distribution of existing resources;

(B) identifying health care needs and informing health care policy;

(C) evaluating the effectiveness of intervention programs on improving patient outcomes;

(D) comparing costs between various treatment settings and approaches;

(E) providing information to consumers and purchasers of health care; and

(F) improving the quality and affordability of patient health care and health care coverage.

(2)(A) The program authorized by this section shall include a consumer health care price and quality information system designed to make available to consumers transparent health care price information, quality information, and such other information as the Board determines is necessary to empower individuals, including uninsured individuals, to make economically sound and medically appropriate decisions.

(B) The Commissioner may require a health insurer covering at least five percent of the lives covered in the insured market in this State to file with the Commissioner a consumer health care price and quality information plan in accordance with rules adopted by the Commissioner.

(C) The Board shall adopt such rules as are necessary to carry out the purposes of this subdivision. The Board's rules may permit the gradual implementation of the consumer health care price and quality information system over time, beginning with health care price and quality information that the Board determines is most needed by consumers or that can be most practically provided to the consumer in an understandable manner. The rules shall permit health insurers to use security measures designed to allow subscribers access to price and other information without disclosing trade secrets to individuals and entities who are not subscribers. The rules shall avoid unnecessary duplication of efforts relating to price and quality reporting by health insurers, health care providers, health care facilities, and others, including activities

undertaken by hospitals pursuant to their community report obligations under section 9405b of this title.

(b) The database shall contain unique patient and provider identifiers and a uniform coding system, and shall reflect all health care utilization, costs, and resources in this State, and health care utilization and costs for services provided to Vermont residents in another state.

(c) Health insurers, health care providers, health care facilities, and governmental agencies shall file reports, data, schedules, statistics, or other information determined by the Board to be necessary to carry out the purposes of this section. Such information may include:

(1) health insurance claims and enrollment information used by health insurers;

(2) information relating to hospitals filed under subchapter 7 of this chapter (hospital budget reviews); and

(3) any other information relating to health care costs, prices, quality, utilization, or resources required by the Board to be filed.

(d) The Board may by rule establish the types of information to be filed under this section, and the time and place and the manner in which such information shall be filed.

(e) Records or information protected by the provisions of the physician-patient privilege under 12

V.S.A. § 1612(a), or otherwise required by law to be held confidential, shall be filed in a manner that does not disclose the identity of the protected person.

(f) The Board shall adopt a confidentiality code to ensure that information obtained under this section is handled in an ethical manner.

(g) Any person who knowingly fails to comply with the requirements of this section or rules adopted pursuant to this section shall be subject to an administrative penalty of not more than $1,000.00 per violation. The Board may impose an administrative penalty of not more than $10,000.00 each for those violations the Board finds were willful. In addition, any person who knowingly fails to comply with the confidentiality requirements of this section or confidentiality rules adopted pursuant to this section and uses, sells, or transfers the data or information for commercial advantage, pecuniary gain, personal gain, or malicious harm shall be subject to an administrative penalty of not more than $50,000.00 per violation. The powers vested in the Board by this subsection shall be in addition to any other powers to enforce any penalties, fines, or forfeitures authorized by law.

(h)(1) All health insurers shall electronically provide to the Board in accordance with standards and procedures adopted by the Board by rule:

(A) their health insurance claims data, provided that the Board may exempt from all or a portion of the filing requirements of this subsection data

reflecting utilization and costs for services provided in this State to residents of other states;

(B) cross-matched claims data on requested members, subscribers, or policyholders; and

(C) member, subscriber, or policyholder information necessary to determine third party liability for benefits provided.

(2) The collection, storage, and release of health care data and statistical information that is subject to the federal requirements of the Health Insurance Portability and Accountability Act ("HIPAA") shall be governed exclusively by the regulations adopted thereunder in 45 C.F.R. Parts 160 and 164.

(A) All health insurers that collect the Health Employer Data and Information Set (HEDIS) shall annually submit the HEDIS information to the Board in a form and in a manner prescribed by the Board.

(B) All health insurers shall accept electronic claims submitted in Centers for Medicare and Medicaid Services format for UB-92 or HCFA-1500 records, or as amended by the Centers for Medicare and Medicaid Services.

(3)(A) The Board shall collaborate with the Agency of Human Services and participants in the Agency's initiatives in the development of a comprehensive health care information system. The collaboration is intended to address the formulation of a description of the data sets that will be included in the comprehensive health care information system, the criteria

and procedures for the development of limited-use data sets, the criteria and procedures to ensure that HIPAA compliant limited-use data sets are accessible, and a proposed time frame for the creation of a comprehensive health care information system.

(B) To the extent allowed by HIPAA, the data shall be available as a resource for insurers, employers, providers, purchasers of health care, and State agencies to continuously review health care utilization, expenditures, and performance in Vermont. In presenting data for public access, comparative considerations shall be made regarding geography, demographics, general economic factors, and institutional size.

(C) Consistent with the dictates of HIPAA, and subject to such terms and conditions as the Board may prescribe by rule, the Vermont Program for Quality in Health Care shall have access to the unified health care database for use in improving the quality of health care services in Vermont. In using the database, the Vermont Program for Quality in Health Care shall agree to abide by the rules and procedures established by the Board for access to the data. The Board's rules may limit access to the database to limited-use sets of data as necessary to carry out the purposes of this section.

(D) Notwithstanding HIPAA or any other provision of law, the comprehensive health care information system shall not publicly disclose any data that contains direct personal identifiers. For the purposes of this section, "direct personal identifiers" include information relating to an

individual that contains primary or obvious identifiers, such as the individual's name, street address, e-mail address, telephone number, and Social Security number.

(i) On or before January 15, 2008 and every three years thereafter, the Commissioner shall submit a recommendation to the General Assembly for conducting a survey of the health insurance status of Vermont residents.

(j)(1) As used in this section, and without limiting the meaning of subdivision 9402(8) of this title, the term "health insurer" includes:

(A) any entity defined in subdivision 9402(8) of this title;

(B) any third party administrator, any pharmacy benefit manager, any entity conducting administrative services for business, and any other similar entity with claims data, eligibility data, provider files, and other information relating to health care provided to a Vermont resident, and health care provided by Vermont health care providers and facilities required to be filed by a health insurer under this section;

(C) any health benefit plan offered or administered by or on behalf of the State of Vermont or an agency or instrumentality of the State; and

(D) any health benefit plan offered or administered by or on behalf of the federal government with the agreement of the federal government.

(2) The Board may adopt rules to carry out the provisions of this subsection, including criteria for the required filing of such claims data, eligibility data, provider files, and other information as the Board determines to be necessary to carry out the purposes of this section and this chapter.

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§ 9410. Health care database [Prior to 2013 Amendment]

(a)(1) The commissioner shall establish and maintain a unified health care data base to enable the commissioner to carry out the duties under this chapter and Title 8, including:

(A) Determining the capacity and distribution of existing resources.

(B) Identifying health care needs and informing health care policy.

(C) Evaluating the effectiveness of intervention programs on improving patient outcomes.

(D) Comparing costs between various treatment settings and approaches.

(E) Providing information to consumers and purchasers of health care.

(F) Improving the quality and affordability of patient health care and health care coverage.

(2)(A) The program authorized by this section shall include a consumer health care price and quality information system designed to make available to consumers transparent health care price information, quality information, and such other information as the commissioner determines is necessary to empower individuals, including uninsured individuals, to make economically sound and medically appropriate decisions.

(B) The commissioner shall convene a working group composed of the commissioner of mental health, the commissioner of Vermont health access, health care consumers, the office of the health care ombudsman, employers and other payers, health care providers and facilities, the Vermont program for quality in health care, health insurers, and any other individual or group appointed by the commissioner to advise the commissioner on the development and implementation of the consumer health care price and quality information system.

(C) The commissioner may require a health insurer covering at least five percent of the lives covered in the insured market in this state to file with the commissioner a consumer health care price and quality information plan in accordance with rules adopted by the commissioner.

(D) The commissioner shall adopt such rules as are necessary to carry out the purposes of this subdivision. The commissioner's rules may permit the gradual implementation of the consumer health care price

and quality information system over time, beginning with health care price and quality information that the commissioner determines is most needed by consumers or that can be most practically provided to the consumer in an understandable manner. The rules shall permit health insurers to use security measures designed to allow subscribers access to price and other information without disclosing trade secrets to individuals and entities who are not subscribers. The regulations shall avoid unnecessary duplication of efforts relating to price and quality reporting by health insurers, health care providers, health care facilities, and others, including activities undertaken by hospitals pursuant to their community report obligations under section 9405b of this title.

(b) The database shall contain unique patient and provider identifiers and a uniform coding system, and shall reflect all health care utilization, costs and resources in this state, and health care utilization and costs for services provided to Vermont residents in another state.

(c) Health insurers, health care providers, health care facilities, and governmental agencies shall file reports, data, schedules, statistics, or other information determined by the commissioner to be necessary to carry out the purposes of this section. Such information may include:

(1) health insurance claims and enrollment information used by health insurers;

(2) information relating to hospitals filed under subchapter 7 of this chapter (hospital budget reviews); and

(3) any other information relating to health care costs, prices, quality, utilization, or resources required to be filed by the commissioner.

(d) The commissioner may by rule establish the types of information to be filed under this section, and the time and place and the manner in which such information shall be filed.

(e) Records or information protected by the provisions of the physician-patient privilege under 12 V.S.A. § 1612(a), or otherwise required by law to be held confidential, shall be filed in a manner that does not disclose the identity of the protected person.

(f) The commissioner shall adopt a confidentiality code to ensure that information obtained under this section is handled in an ethical manner.

(g) Any person who knowingly fails to comply with the requirements of this section or rules adopted pursuant to this section shall be subject to an administrative penalty of not more than $1,000.00 per violation. The commissioner may impose an administrative penalty of not more than $10,000.00 each for those violations the commissioner finds were willful. In addition, any person who knowingly fails to comply with the confidentiality requirements of this section or confidentiality rules adopted pursuant to this

section and uses, sells, or transfers the data or information for commercial advantage, pecuniary gain, personal gain, or malicious harm shall be subject to an administrative penalty of not more than $50,000.00 per violation. The powers vested in the commissioner by this subsection shall be in addition to any other powers to enforce any penalties, fines, or forfeitures authorized by law.

(h)(1) All health insurers shall electronically provide to the commissioner in accordance with standards and procedures adopted by the commissioner by rule:

(A) their health insurance claims data, provided that the commissioner may exempt from all or a portion of the filing requirements of this subsection data reflecting utilization and costs for services provided in this state to residents of other states;

(B) cross-matched claims data on requested members, subscribers, or policyholders; and

(C) member, subscriber, or policyholder information necessary to determine third party liability for benefits provided.

(2) The collection, storage, and release of health care data and statistical information that is subject to the federal requirements of the Health Insurance Portability and Accountability Act ("HIPAA") shall be governed exclusively by the rules adopted thereunder in 45 CFR Parts 160 and 164.

(A) All health insurers that collect the Health Employer Data and Information Set (HEDIS) shall

annually submit the HEDIS information to the commissioner in a form and in a manner prescribed by the commissioner.

(B) All health insurers shall accept electronic claims submitted in Centers for Medicare and Medicaid Services format for UB-92 or HCFA-1500 records, or as amended by the Centers for Medicare and Medicaid Services.

(3)(A) The commissioner shall collaborate with the agency of human services and participants in agency of human services initiatives in the development of a comprehensive health care information system. The collaboration is intended to address the formulation of a description of the data sets that will be included in the comprehensive health care information system, the criteria and procedures for the development of limited use data sets, the criteria and procedures to ensure that HIPAA compliant limited use data sets are accessible, and a proposed time frame for the creation of a comprehensive health care information system.

(B) To the extent allowed by HIPAA, the data shall be available as a resource for insurers, employers, providers, purchasers of health care, and state agencies to continuously review health care utilization, expenditures, and performance in Vermont. In presenting data for public access, comparative considerations shall be made regarding geography, demographics, general economic factors, and institutional size.

(C) Consistent with the dictates of HIPAA, and subject to such terms and conditions as the commissioner may prescribe by regulation, the Vermont program for quality in health care shall have access to the unified health care database for use in improving the quality of health care services in Vermont. In using the database, the Vermont program for quality in health care shall agree to abide by the rules and procedures established by the commissioner for access to the data. The commissioner's rules may limit access to the database to limited-use sets of data as necessary to carry out the purposes of this section.

(D) Notwithstanding HIPAA or any other provision of law, the comprehensive health care information system shall not publicly disclose any data that contains direct personal identifiers. For the purposes of this section, "direct personal identifiers" include information relating to an individual that contains primary or obvious identifiers, such as the individual's name, street address, e-mail address, telephone number, and Social Security number.

(i) On or before January 15, 2008 and every three years thereafter, the commissioner shall submit a recommendation to the general assembly for conducting a survey of the health insurance status of Vermont residents.

(j)(1) As used in this section, and without limiting the meaning of subdivision 9402(8) of this title, the term "health insurer" includes:

(A) any entity defined in subdivision 9402(8) of this title;

(B) any third party administrator, any pharmacy benefit manager, any entity conducting administrative services for business, and any other similar entity with claims data, eligibility data, provider files, and other information relating to health care provided to Vermont resident, and health care provided by Vermont health care providers and facilities required to be filed by a health insurer under this section;

(C) any health benefit plan offered or administered by or on behalf of the state of Vermont or an agency or instrumentality of the state; and

(D) any health benefit plan offered or administered by or on behalf of the federal government with the agreement of the federal government.

(2) The commissioner may adopt rules to carry out the provisions of this subsection, including standards and procedures requiring the registration of persons or entities not otherwise licensed or registered by the commissioner and criteria for the required filing of such claims data, eligibility data, provider files, and other information as the commissioner determines to be necessary to carry out the purposes of this section and this chapter.

REGULATION H-2008-01

Vermont Healthcare Claims Uniform Reporting and Evaluation System ("VHCURES")

Section 1: Purpose

The purpose of this rule is to set forth the requirements for the submission of health care claims data, member eligibility data, and other information relating to health care provided to Vermont residents or by Vermont health care providers and facilities by health insurers, managed care organizations, third party administrators, pharmacy benefit managers and others to the Department of Banking, Insurance, Securities and Health Care Administration and conditions for the use and dissemination of such claims data, all as required by and consistent with the purposes of 18 V.S.A. §9410.

Section 2: Authority

This rule is issued pursuant to the authority vested in the Commissioner of the Department of Banking, Insurance, Securities and Health Care Administration by 18 V.S.A. §9410, as well as 8 V.S.A. §15 and other applicable portions of Chapter 221 of Title 18.

Section 3: Definitions As used in this Rule

A. "BISHCA" or "Department" means the Vermont Department of Banking, Insurance, Securities and Health Care Administration.

B. “Capitated services” means services rendered by a provider through a contract in which payment are based upon a fixed dollar amount for each member on a monthly basis.

C. “Cell size” means the count of persons that share a set of characteristics contained in a statistical table.

D. “Charge” means the actual dollar amount charged on the claim.

E. “Co-insurance” means the percentage a member pays toward the cost of a covered service.

F. “Commissioner” means the commissioner of the Department of Banking, Insurance, Securities and Health Care Administration or his or her designee.

G. “Co-payment” means the fixed dollar amount a member pays to a health care provider at the time a covered service is provided or the full cost of a service when that is less than the fixed dollar amount.

H. “Current Procedural Terminology (CPT)” means a medical code set of physician and other services, maintained and copyrighted by the American Medical Association (AMA), and adopted by the U.S. Secretary of Health and Human Services as the standard for reporting physician and other services on standard transactions.

I. “Data set” means a collection of individual data records, whether in electronic or manual files.

J. “Deductible” means the total dollar amount a member pays towards the cost of covered services

over an established period of time before the contracted third-party payer makes any payments.

K. "De-identified health information" means information that does not identify an individual patient, member or enrollee and with respect to which no reasonable basis exists to believe that the information can be used to identify an individual patient, member or enrollee. De-identification means that health information is not individually identifiable and requires the removal of Direct Personal Identifiers associated with patients, members or enrollees.

L. "Direct personal identifiers" is information relating to an individual patient, member or enrollee that contains primary or obvious identifiers, including:

(1) Names;

(2) Business names when that name would serve to identify a person;

(3) Postal address information other than town or city, state, and 5-digit zip code;

(4) Specific latitude and longitude or other geographic information that would be used to derive postal address;

(5) Telephone and fax numbers;

(6) Electronic mail addresses;

(7) Social security numbers;

(8) Vehicle Identifiers and serial numbers, including license plate numbers;

(9) Medical record numbers;

(10) Health plan beneficiary numbers;

(11) Certificate and license numbers;

(12) Internet protocol (IP) addresses and uniform resource locators (URL) that identify a business that would serve to identify a person;

(13) Biometric identifiers, including finger and voice prints; and

(14) Personal photographic images.

M. "Disclosure" means the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.

N. "Encrypted identifier" is a code or other means of record identification to allow patients, members or enrollees to be tracked across the data set without revealing their identity. Encrypted identifiers are not direct identifiers.

O. "Encryption" means a method by which the true value of data has been disguised in order to prevent the identification of persons or groups, and which does not provide the means for recovering the true value of the data.

P. "Health benefit plan" means a policy, contract, certificate or agreement entered into, or offered by a health insurer to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services.

Q. "Healthcare claims data" means information consisting of or derived directly from member eligibility files, medical claims files, pharmacy claims files and other related data pursuant to the Vermont Healthcare Claims Uniform Reporting and Evaluation System (VHCURES) in effect at the time of the data submission. "Healthcare claims data" does not include analysis, reports, or studies containing information from health care claims data sets if those analyses, reports, or studies have already been released in response to another request for information or as part of a general distribution of public information by BISHCA.

R. "Healthcare premium" means the dollar amount charged for any policies offered by health insurers which partially or fully cover the cost of health care services.

S. "Healthcare Common Procedure Coding System (HCPCS)" means a medical code set that identifies health care procedures, equipment, and supplies for claim submission purposes. These are often known as "local codes".

T. "Health care" means care, services, or supplies related to the health of an individual. It includes but is not limited to (1) preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and (2) sale or dispensing of a drug, device,

equipment, or other item in accordance with a prescription [45 CFR § 160.103].

U. "Health care facility" shall be defined as per 18 V.S.A §9432, as amended from time to time.

V. "Health care provider" means a person, partnership, corporation, facility or institution, licensed or certified or authorized by law to provide professional health care service in this state to an individual during that individual's medical care, treatment or confinement, as per 18 V.S.A. §9432.

W. "Health information" means any information, whether oral or recorded in any form or medium, that 1) is created or received by a health-care provider, health plan, public health authority, employer, life insurer, school or university, or health-care clearinghouse; and 2) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual shall be as defined in 45 CFR § 160.103.

X. "Health insurer" means those entities defined in 18 V.S.A. §§ 9402 and 9410(j)(1), and includes any health insurance company, nonprofit hospital and medical service corporation, managed care organization, third party administrator, pharmacy benefit manager, and any entity conducting administrative services for business or possessing claims data, eligibility data, provider files, and other information relating to health care provided to Vermont residents or by Vermont health care providers and facilities. The

term may also include, to the extent permitted under federal law, any administrator of an insured, self-insured, or publicly funded health care benefit plan offered by public and private entities.

Y. "HIPAA" means the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.

Z. "Indirect personal identifiers" means information relating to an individual patient, member or enrollee that a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods could apply to render such information individually identifiable by using such information alone or in combination with other reasonably available information.

Aa. "International Classification of Diseases" or "ICD" shall mean that medical code set maintained by the World Health Organization.

Ab. "Mandated Reporter" means a health insurer as defined herein and at 18 V.S.A. §9410(j)(1) with two hundred (200) or more enrolled or covered members in each month during a calendar year, including both Vermont residents and any nonresidents receiving covered services provided by Vermont health care providers and facilities.

Ac. "Medical claims file" means a data file composed of service level remittance information for all non-denied adjudicated claims for each billed service including, but not limited to member demographics, provider information, charge/payment

information, and clinical diagnosis and procedure codes, and shall include all claims related to behavioral or mental health.

Ad. "Member" means the insured subscriber and any spouse and/or dependent covered by the subscriber's policy.

Ae. "Member eligibility file" means a data file containing demographic information for each individual member eligible for medical or pharmacy benefits for one or more days of coverage at any time during the reporting month.

Af. "Patient" means any person in the data set that is the subject of the activities of the claim performed by the health care provider.

Ag. "Payer" means a third-party payer or third-party administrator.

Ah. "Payment" means the actual dollar amount paid for a claim by a health insurer.

Ai. "Personal identifiers" means information relating to an individual that contains direct or indirect identifiers to which a reasonable basis exists to believe that the information can be used to identify an individual.

Aj. "Pharmacy Benefit Manager" or "PBM" means a person or entity that performs pharmacy benefit management as that term is defined at 18 V.S.A. §9471(4). The term includes a person or entity in a contractual or employment relationship with an entity performing pharmacy benefit management for a health plan.

Ak. "Pharmacy claims file" means a data file containing service level remittance information from all non-denied adjudicated claims for each prescription including, but not limited to: member demographics; provider information; charge/payment information; and national drug codes.

Al. "Prepaid amount" means the fee for the service equivalent that would have been paid for a specific service if the service had not been capitated.

Am. "Principal Investigator" means the person in charge of a project that makes use of limited use research health care claims data sets. The principal investigator is the custodian of the data and is responsible for compliance with all restrictions, limitations and conditions of use associated with the data release.

An. "Public Use Data Set" means a publicly available data set containing only the public use data elements specified in this Rule as unrestricted data elements in Appendix J.

Ao. "Reporter" means a health insurer as defined herein and at 18 V.S.A. §9410(j)(1), and shall include Voluntary Reporters as defined herein.

Ap. "Subscriber" means the individual responsible for payment of premiums or whose employment is the basis for eligibility for membership in a health benefit plan.

Aq. "Third-party Administrator" means any person who, on behalf of a health insurer or purchaser of health benefits, receives or collects charges, contributions or premiums for, or adjusts or settles

claims on or for residents of this State or Vermont health care providers and facilities.

Ar. "Vermont Healthcare Claims Uniform Reporting and Evaluation System" or "VHCURES" means the Department's system for the collection, management and reporting of eligibility, claims and related data submitted pursuant to 18 V.S.A. § 9410.

As. "Voluntary Reporter" includes any entity other than a mandated reporter, including any health benefit plan offered or administered by or on behalf of the federal government where such plan, with the agreement of the federal government, voluntarily submits data to the BISHCA commissioner for inclusion in the database on such terms as may be appropriate.

Section 4: Reporting Requirements

Registration and Reporting Requirements

A. VHCURES Reporter Registration. On an annual basis prior to December 31, Health Insurers shall register with the Department on a form established by the Commissioner and identify whether health care claims are being paid for members who are Vermont residents and whether health care claims are being paid for non-residents receiving covered services from Vermont health care providers or facilities. Where applicable, the completed form shall identify the types of files to be submitted per Section 5. This form shall be submitted to BISHCA or its designee. See Appendix F.

B. Third Party Administrator Registration. Any person or entity that provides third party administration services, a third party administrator or "TPA" as defined in Section 3, shall register with the Department on a form established by the Commissioner, both before doing business in Vermont and on an annual basis prior to December 31 thereafter. 18 V.S.A. §9410. See Appendix G.

C. Pharmacy Benefit Manager Registration. Any person or entity that performs pharmacy benefit management (a pharmacy benefit manager or "PBM") shall register with the Department on a form established by the Commissioner both before doing business in Vermont and on an annual basis prior to December 31. 18 V.S.A. §9421. The registration requirement includes persons or entities in a contractual or employment relationship with a health insurer or PBM performing pharmacy benefit management for a health plan with Vermont enrollees or beneficiaries. 18 V.S.A. §9471. See Appendix H.

D. Health Insurers shall regularly submit medical claims data, pharmacy claims data, member eligibility data, provider data, and other information relating to health care provided to Vermont residents and health care provided by Vermont health care providers and facilities to both Vermont residents and non-residents in specified electronic format to the Department for each health line of business (Comprehensive Major Medical, TPA/ASO, Medicare Supplemental, Medicare Part C, and Medicare Part D) per the

data submission requirements contained in the appendices to this Rule.

E. Voluntary Reporters may, with the permission of the Commissioner, participate in VHCURES and submit medical claims files, pharmacy claims files, member eligibility files, provider data, and other information relating to health care provided to Vermont residents and health care provided by Vermont health care providers and facilities to both Vermont residents and non-residents in specified electronic format to the Department per the data submission requirements contained in the appendices to this Rule.

Section 5: Required Healthcare Data Files

Mandated Reporters shall submit to BISHCA or its designee health care claims data for all members who are Vermont residents and all non-residents who received covered services provided by Vermont health care providers or facilities in accordance with the requirements of this section. Each Mandated Reporter is also responsible for the submission of all health care claims processed by any sub-contractor on its behalf unless such subcontractor is already submitting the identical data as a Mandated Reporter in its own right. The health care claims data submitted shall include, where applicable, a member eligibility file containing records associated with each of the claims files reported: a medical claims file and a pharmacy claims file. The data submitted shall also include supporting definition files for payer specific

provider specialty taxonomy codes and procedure and/or diagnosis codes.

A. General Requirements for Data Submission

(1) Adjustment Records. Adjustment records shall be reported with the appropriate positive or negative fields with the medical and pharmacy claims file submissions. Negative values shall contain the negative sign before the value. No sign shall appear before a positive value.

(2) Behavioral or Mental Health Claims. All claims related to behavioral or mental health shall be included in the medical claims file.

(3) Capitated Service Claims. Claims for capitated services shall be reported with all medical and pharmacy claims file submissions.

(4) Claims Records. Records for the medical and pharmacy claims file submissions shall be reported at the visit, service, or prescription level. The submission of the medical and pharmacy claims is based upon the paid dates and not upon the dates of service associated with the claims.

(5) Codes and Encryption Requirements

(a) Code Sources. Unless otherwise specified in this regulation, the code sources listed and described in Appendix A shall be utilized in association with the member eligibility file and medical and pharmacy claims file submissions.

(b) Member Identification Code. Reporters shall assign to each of their members a unique identification code that is the member's social security number. If a Reporter does not collect the social security numbers for all members, the Reporter shall use the social security number of the subscriber and then assign a discrete two-digit suffix for each member under the subscriber's contract.

If the subscriber's social security number is not collected by the Reporter, a version of the subscriber's certificate or contract number shall be used in its place. The discrete two-digit suffix shall also be used with the certificate or contract number. The certificate or contract number with the two-digit suffix shall be at least eleven but not more than sixty-four characters in length.

The social security number of the member/subscriber and the subscriber and member names shall be encrypted prior to submission by the Reporter utilizing a standard encryption methodology provided by BISHCA or its designee. The unique member identification code assigned by each Reporter shall remain with each member/subscriber for the entire period of coverage for that individual.

(c) Specific/Unique Coding. With the exception of provider, provider specialty, and

procedure/diagnosis codes, specific or unique coding systems shall not be permitted as part of the health care claims data set submission.

(6) Co-Insurance/Co-Payment. Co-insurance and co-payment are to be reported in two separate fields in the medical and pharmacy claims file submissions.

(7) Coordination of Benefits Claims. Claims where multiple parties have financial responsibility shall be included with all medical and pharmacy claims file submissions.

(8) Denied Claims. Denied claims shall be excluded from all medical and pharmacy claims file submissions. When a claim contains both fully processed/paid service lines and partially processed or denied service lines, only the fully processed/paid service lines shall be included as part of the health care claims data set submittal.

(9) Eligibility Records. Records for the member eligibility file submission shall be reported at the individual member level with one record submitted for each claim type. If a member is covered as both a subscriber and a dependent on two different policies during the same month, two records must be submitted. If a member has 2 contract numbers for 2 different coverage types, 2 member eligibility records shall be submitted.

(10) Exceptions.

(a) Medical Claims File Exclusions. All claims related to services provided under stand-alone health care policies shall be excluded if the services are not covered by comprehensive medical insurance policies and are provided on a stand-alone basis for:

1. Specific disease;

2. Accident:

3. Injury;

4. Hospital indemnity;

5. Disability:

6. Long-term care;

7. Student liability;

8. Vision coverage; or

9. Durable medical equipment.

(b) Claims for pharmacy services containing national drug codes are to be included in the pharmacy claims file, but excluded from the medical claims file.

(c) Member Eligibility File Exclusions. Members without medical or pharmacy coverage for the month reported shall be excluded.

(11) File Format. Each file submission shall be an ASCII file, variable field length, and asterisk delimited. When asterisks are used in any

field values, the entire value shall be enclosed in double quotes.

(12) Insured Group or Policy Number Key Look-up Table. Reporters are required to submit a key look-up table when submitting member eligibility files. The key look-up table shall link Insured Group or Policy Number (ME006) to the name of the group associated with each Insured Group or Policy Number, but shall not identify any individual policyholders in connection with non-group policies.

(13) Header and Trailer Records. Each member eligibility file and each medical and pharmacy claims file submission shall contain a header record and a trailer record. The header record is the first record of each separate file submission and the trailer record is the last. The header and trailer record formats shall be as detailed in Appendices B-1 and B-2.

(14) Pharmacy Claims. Claims for pharmacy services shall be included in the following files:

(a) If the pharmacy claims are covered under the medical benefit then the claim shall be included in the medical claims file and not the pharmacy claims file; and

(b) If the claim is covered under the prescription benefit then the claim shall be included in the pharmacy claims file.

(15) Prepaid Amount. Any prepaid amounts are to be reported in a separate field in the medical and pharmacy claims file submissions.

(16) Supplemental Health Insurance. Claims related to supplemental health insurance are to be included if the policies are for health care services entirely excluded by the Medicare, Tricare, or other publicly funded health benefit programs.

B. Detailed File Specifications.

(1) Filled Fields. All required fields shall be filled where applicable. Non-required text, date, and integer fields shall be set to null when unavailable. Non-applicable decimal fields shall be filled with one zero and shall not include decimal points when unavailable.

(2) Position. All text fields are to be left justified. All integer and decimal fields are to be right justified.

(3) Signs. Positive values are assumed and need not be indicated as such. Negative values must be indicated with a minus sign and must appear in the left-most position of all integer and decimal fields. Over-punched signed integers or decimals are not to be utilized.

(4) Individual Elements and Mapping. Individual data elements, data types, field lengths, field description/code assignments, and mapping locators (UB-04, HCFA 1500, ANSI X12N 270/271, 835, 837) for each file shall be as detailed in the following appendices:

(a) (1) Member Eligibility File Specifications – Appendix C-1

(2) Member Eligibility File Mapping to National Standard Formats – Appendix C-2

(b) (1) Medical Claims File Specifications – Appendix D-1

(2) Medical Claims File Mapping to National Standard Formats – Appendix D-2

(c) (1) Pharmacy Claims File Specifications – Appendix E-1

(2) Pharmacy Claims File Mapping to National Standard Formats – Appendix E-2

Section 6: Submission Requirements

Data submission requirements shall be as detailed in the attached appendices.

A. Registration Form. It is the responsibility of each Health Insurer to resubmit or amend the registration form required by Section 4 (A) whenever modifications occur relative to the data files or contact information.

B. File Organization. The member eligibility file, medical claims file and pharmacy claims file shall be submitted to BISHCA or its designee as separate ASCII files. Each record shall terminate with a carriage return (ASCII 13) or a carriage return line feed (ASCII 13, ASCII 10).

C. Filing Media. Files shall be submitted utilizing one of the following media: diskette (1.44 MB),

CD-ROM (650 MB), DVD, secure SSL web upload interface, or electronic transmission through a File Transfer Protocol. E-mail attachments shall not be accepted. Space permitting, multiple data files may be submitted utilizing the same media if the external label identifies the multiple files.

D. Transmittal Sheet. All file submissions on physical media shall be accompanied by a hard copy transmittal sheet containing the following information: identification of the Reporter, file name, type of file, data period(s), date sent, record count(s) for the file(s), and a contact person with telephone number and E-mail address. The information on the transmittal sheet shall match the information on the header and trailer records. See Appendix I.

E. Testing of Files. At least sixty days prior to the initial submission of the files or whenever the data element content of the files as described in Section 5 is subsequently altered, each Reporter shall submit to BISHCA or its designee a data set for comparison to the standards listed in Section 7. The size, based upon a calendar period of one month, quarter, or year, of the data files submitted shall correspond to the filing period established for each Reporter under subsection I of this Section.

F. Rejection of Files. Failure to conform to subsections A, B, or C of this Section shall result in the rejection and return of the applicable data file(s). All rejected and returned files shall be resubmitted in the appropriate, corrected form to BISHCA or its designee within 10 days.

G. Replacement of Data Files. No Reporter may replace a complete data file submission more than one year after the end of the month in which the file was submitted unless it can establish exceptional circumstances for the replacement. Any replacements after this period must be approved by BISHCA. Individual adjustment records may be submitted with any monthly data file submission.

H. Run-Out Period. Reporters shall submit medical and pharmacy claims files for at least a six month period following the termination of coverage date for all members who are Vermont residents or non-residents receiving covered services provided by Vermont health care providers or facilities.

I. Data Submission Schedule. The reporting period for submission of each specified file listed in Section 5 shall be determined on a separate basis for Vermont members and non-resident members by the highest total number of Vermont resident members or non-resident members receiving covered services provided by Vermont providers or facilities for which claims are being paid for any one month of the calendar year. Data files are to be submitted in accordance with the following schedule:

Total # of Members	Reporting Period	Reporting Schedule
≥2,000	Monthly	Prior to the end of the month following the month in which claims were paid
500-1,999	Quarterly	Prior to April 30, July 31, October 31, January 31 for each preceding calendar quarter in which claims were paid
200-499	Annually	Prior to April 30 of the following year for the preceding twelve months in which claims were paid
<200	N/A	

If the data files submitted by an individual Reporter support or are related to the files submitted by another Reporter, BISHCA shall establish a filing period for the parties involved.

Section 7: Compliance with Data Standards

A. Standards. BISHCA or its designee shall evaluate each member eligibility file, medical claims file and pharmacy claims file in accordance with the following standards:

(1) The applicable code for each data element shall be as identified in Appendices C-1, D-1,

and E-1 and shall be included within eligible values for the element;

(2) Coding values indicating "data not available", "data unknown", or the equivalent shall not be used for individual data elements unless specified as an eligible value for the element;

(3) Member sex, diagnosis and procedure codes, and date of birth and all other date fields shall be consistent within an individual record;

(4) Member identifiers shall be consistent across files; and

(5) Files submitted shall not contain direct personal identifiers.

B. Notification. Upon completion of this evaluation, BISHCA or its designee will promptly notify each Reporter whose data submissions do not satisfy the standards for any reporting period. This notification will identify the specific file and the data elements that are determined to be unsatisfactory.

C. Response. Each Reporter notified under subsection 7.B shall resubmit within 60 days of the date of notification with the required changes.

D. Compliance. Failure to file, report, or correct health care claims data sets in accordance with the provisions of this regulation may be considered a violation of 18 V.S.A. § 9410(g).

Section 8: Procedures for the Approval and Release of Claims Data

The requirements, procedures and conditions under which persons other than the Department may have access to health care claims data sets and related information received or generated by the Department or its designee pursuant to this regulation shall depend upon the requestor and the characteristics of the particular information requested, all as set forth below.

A. Classification of Data Elements

(1) Unrestricted Data Elements: Data elements designated in Appendix J as "Unrestricted" shall be available for general use and public release as part of a Public Use File.

(2) Restricted Data Elements: Data elements designated in Appendix J as "Restricted" shall not be available for use and release outside the Department except as part of a Limited Use Research Health Care Claims Data Set approved by the commissioner pursuant to the requirements of this regulation.

(3) Unavailable Data Elements: Data elements which are not designated in Appendix J as either Unrestricted or Restricted, or are designated as "Unavailable", shall not be available for release or use outside the Department in any data set or disclosed in publicly released reports in any circumstance.

B. Public Use Data Sets: Release and Availability

(1) Unrestricted Data Elements collected or generated by the Department or its designee

shall be made available in public use files and provided to any person upon written request, except where otherwise prohibited by law.

(2) The Department shall maintain a public record of all requests for and releases of public use data sets.

C. Limited Use Health Care Claims Research Data Sets – Release and Availability

(1) Limited Use Health Care Claims Research Data Sets shall be those sets which contain restricted data elements, shall not be available to the general public and shall be released to a requestor only for the purpose of research upon a determination by the Commissioner that the following conditions have been met:

(a) Application: Any person requesting access to or use of Limited Use Health Care Claims Research Data Sets shall submit an application, in written and electronic form, to the Commissioner disclosing the information listed below. Studies utilizing data sets for longer than 2 years may be required to reapply.

(1) Identity of principal investigator:

(a) Name, address, and phone number;

(b) Organizational affiliation;

(c) Professional qualification; and

(d) Phone number of principal investigator's contact person, if any.

(2) Identity of person requesting access, including any entities for whom that person is acting in requesting the data.

(a) Name, address, and phone number;

(b) Organizational affiliation;

(c) Professional qualification; and

(d) Name and phone number of contact person.

(3) Identity of and qualifications of any other persons who may have access to the data.

(4) A detailed research protocol, to include:

(a) A summary of background, purposes, and origin of the research;

(b) A statement of the health-related problem or issue to be addressed by the research;

(c) The research design and methodology, including either the topics of exploratory research or the specific research hypotheses to be tested;

(d) The procedures that will be followed to maintain the confidentiality of any data or copies of

records provided to the principal investigator or other persons; and

(e) The intended research completion date;

(5) Particular data set requested, including:

(a) The time period of the data requested;

(b) The specific data elements or fields of information required;

(c) A justification of the need for each restricted element or field, as identified in the data release schedule;

(d) The minimum needed specificity of the requested data elements, including the manner in which the data may be recoded by the department to be less specific;

(e) The selection criteria for the minimum needed data records required; and

(f) Any particular format or layout of data requested by the principal investigator.

(6) Any changes to information submitted as part of an application pursuant to (a)(1)-(4) shall require notice

to the Department by the applicant and shall be subject to the approval of the Commissioner.

(b) The person or entity requesting access and the principal investigator or investigators shall be subject to the following requirements and limitations and shall, in addition, sign and submit a data use agreement acknowledging and accepting these same provisions as a necessary condition to any data access:

(1) Use of data for any purpose other than as specified in the application and approved by the Commissioner shall be prohibited;

(2) Appropriate safeguards to protect the confidentiality of the data and prevent unauthorized use of the data shall be established;

(3) The use or disclosure, sale, or dissemination of the data set or statistical tabulations derived from the data set to any person or organization for any purpose other than as described in the application and as permitted by the data use agreement shall be prohibited without the express written consent of the Commissioner.

(4) The use or disclosure, sale, or dissemination of any information contrary to law shall be prohibited;

(5) No person shall disclose the identity of patients, employer groups or purchaser groups from information contained in the limited use data set;

(6) No person shall disclose any of the information that has been encrypted or removed from the data;

(7) The content of cells that contain counts of persons in statistical tables in which the cell size is more than 0 and less than 5 shall not be disclosed, published or made public in any manner except as "<5";

(8) The publication, dissemination or disclosure of any information that could be used to identify providers of abortion services shall be prohibited;

(9) Any use or disclosure of the information that is contrary to the Data Use Agreement or this Regulation shall be reported to the Department within five (5) days of when the principal investigator becomes aware of such disclosure.

(10) The Department and the "Vermont Healthcare Claims Uniform Reporting and Evaluation System" shall be acknowledged as the source and owner of the data in any and all public reports, publications, or

presentations generated from the data;

(11) Written materials shall prominently state that the analyses, conclusions and recommendations drawn from such data are solely those of the requestor or principal investigator and are not necessarily those of the Department;

(12) The Department shall be provided with a copy of any proposed report or publication containing information derived from the data at least 15 days prior to any publication or release to allow the department to review the proposed report or publication and confirm that the conditions of the agreement have been applied. When multiple reports of a similar nature will be created from the data, the Department may, on request, waive the requirement that any subsequent reports or publications be provided to the Department prior to release by the requesting party

(13) Data elements shall not be retained for any period of time beyond that necessary to fulfill the requirements of the data request.

(14) Within 30 days after the scheduled completion date of the project, the requestor shall delete, destroy or

otherwise render the data unreadable, so certifying by submitting a written notice to the Department or by reapplying for approval if the end date of the project needs to be extended;

(15) Any draft reports or publications supplied to the department shall be considered confidential and exempt from public review under 1 V.S.A. §315 et seq. and shall not be released by the Department; and

(16) Failure to adhere to the data use agreement or the limitations and restrictions detailed above will be cause for immediate recall by the Department of the data, revocation of permission to use the data, and grounds for civil or administrative enforcement action by the Department under applicable Vermont state law.

(c) The Department shall establish a claims data release advisory committee with a chair person and members appointed annually by the Commissioner, to provide non-binding advice and opinion to the Commissioner, as and when requested, on the merits of applications for access to limited use data sets. If the Commissioner has requested a review of the application, the claims data release advisory committee shall provide the

Commissioner with any comment on the merits of the application and the research protocol described therein within thirty (30) days. The committee shall be comprised of seven (7) members and include:

(1) At least one member representing health insurers;

(2) At least one member representing health care facilities;

(3) At least one member representing health care providers;

(4) At least one member representing purchasers of health insurance or health benefits; and

(5) At least one member representing healthcare researchers.

(2) The Commissioner may approve the release of limited use data sets only when the Commissioner is satisfied as to the following:

(a) The application submitted is complete and the requesting individuals or entities and principal investigator have signed a data use agreement as specified;

(b) Procedures to ensure the confidentiality of any patient and any confidential data are documented;

(c) The qualifications of the investigator and research staff, as evidenced by:

(1) Training and previous research, including prior publications; and

(2) An affiliation with a university, private research organization, medical center, state agency, or other qualified institutional entity.

(d) No other state or federal law or regulation prohibits release of the requested information.

(3) If the Commissioner declines to release the requested limited use data sets within 60 days of receipt of a complete application, the Department shall give written notice of the basis for denial of the application and the requestor shall have leave to resubmit or supplement the application to address the Commissioner's concerns. Any adverse decision regarding an application may be appealed within 30 days by filing a request for hearing with the Commissioner pursuant to Department Rule 82-1.

Section 9: Prices for Data Sets, Fees for Programming and Report Generation, Duplication Rates

This Section lists the prices for data sets from the Vermont Healthcare Claims Uniform Reporting and Evaluation System, including the fees for programming and report generation, duplicating charges and other costs associated with the production and transmission of data sets approved for release by the Department.

A. An annual public use file consisting of unrestricted fields and data elements shall be made available to any person upon request at the cost required for the Department to process, package and ship the data set, including any electronic medium used to store the data.

B. Limited Use Research Health Care Claims Data Sets approved by the Department shall be made available to the requesting party at the cost charged by the Department's designated vendor to program and process the requested data extract, including any consulting services and costs to package and ship the data set on particular electronic medium.

C. Payments are due in full from the requesting party within thirty days of receipt of BISHCA data sets, files, reports, or other released material.

Section 10: Enforcement

Violations of data submission requirements, confidentiality requirements, data use limitations or any other provisions of this rule shall be subject to sanction by the Commissioner as set out in 18 V.S.A. §9410 in addition to any other powers granted to the Commissioner to investigate, subpoena, fine or seek other legal or equitable remedies.

Section 11: Severability

If any provision of this regulation or the application thereof to any person or circumstance is for any

reason held to be invalid, the remainder of the regulation and the application of such provisions to other persons or circumstances shall be not affected thereby.