No. 14-181

IN THE

Supreme Court of the United States

ALFRED GOBEILLE, in his official capacity as chair of the Vermont Green Mountain Care Board,
Petitioner,

v.

LIBERTY MUTUAL INSURANCE COMPANY,
Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR RESPONDENT

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QUESTION PRESENTED

Vermont has enacted legislation and issued regulations that require "health insurers" to regularly submit to the State "medical claims data, pharmacy claims data, member eligibility data, provider data, and other information relating to health care" for use in Vermont's unified health care database. Health insurers—which Vermont defines as including, "to the extent permitted under federal law," the administrators of self-insured health care benefit plans—must submit annual registration forms and report claims data at specified intervals (monthly for some insurers) in a format prescribed by the State.

The question presented is:

Whether the Employee Retirement Income Security Act of 1974 preempts Vermont's reporting mandates insofar as they require the submission of data about claims paid under the terms of self-insured plans governed by ERISA.

PARTIES TO THE PROCEEDING

The defendant in the district court and the original appellee was Commissioner Stephen W. Kimbell, in his official capacity as the Vermont Commissioner of Banking, Insurance, Securities, and Health Care Administration. Commissioner Susan L. Donegan was substituted for Commissioner Kimbell when she replaced him in office. The petition in this matter was filed by Alfred J. Gobeille, in his official capacity as Chair of the Green Mountain Care Board. Chair Gobeille was not a party to the proceedings below, and as explained in the brief in opposition (at 10-13), he is not a party to this action entitled to petition for certiorari under 28 U.S.C. §1254(1).

Respondent Liberty Mutual Insurance Company was the plaintiff in the district court and the appellant in the court of appeals.

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JURISDICTION

Petitioner invokes this Court's jurisdiction under 28 U.S.C. §1254(1), but as previously explained (Br. in Opp. 10-13), this Court lacks jurisdiction over the petition because the Chair of the Green Mountain Care Board is not a proper party to seek review of the court of appeals' decision.

CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

The appendix to this brief reproduces the pertinent provisions of the Supremacy Clause, U.S. Const. art. VI, cl. 6; the Employee Retirement Income Security

Act of 1974 (ERISA), 29 U.S.C. §§1001 *et seq.*; Vermont's Database Statute, 18 V.S.A. §9410; and Vermont's Regulation H-2008-01.

STATEMENT

A. ERISA And The Exclusively National Regulation Of Benefit Plans

A central objective of the Employee Retirement Income Security Act of 1974 (ERISA) was to establish a uniform, national regime governing employee benefit plans. ERISA allows employers to maintain self-funded health benefit plans on a national basis free from state regulation. Traditionally, private health insurance cannot be purchased from companies located outside the insured's home state. Congress recognized, however, that employers increasingly operate nationwide and that a localized approach to benefit plans would be inefficient and detrimental to employees and beneficiaries. To ensure that employee benefit plans can dedicate resources to providing benefits rather than meeting unnecessary administrative costs, Congress made those plans subject to exclusively federal regulation.

ERISA imposes detailed and comprehensive federal requirements on employee benefit plans.[1] Among other things, under ERISA, "[a]ll employee benefit plans must conform to various reporting, disclosure,

[1] ERISA regulates two kinds of employee benefit plans: welfare benefit plans and pension benefit plans. 29 U.S.C. §1002(3). This case concerns a welfare benefit plan, which is established to provide health care benefits to employees and beneficiaries, *id.* §1002(1)(A). Although some aspects of the federal regulation of welfare plans and pension plans are distinct, as discussed below, *see infra* pp. 29-30, the preemption principles for the two kinds of plans are identical.

and fiduciary requirements." *Boggs* v. *Boggs*, 520 U.S. 833, 841 (1997). The statute's reporting and disclosure requirements, codified at 29 U.S.C. §§1021-1031, mandate that employee benefit plans file with the Secretary of Labor annual reports containing specified information. *Id.* §§1021-1024. Plans must also maintain books and records concerning the information disclosed in the various reports they file. *Id.* §1027. In addition, ERISA recognizes the Secretary's broad authority to impose reporting requirements on plans to carry out the purposes of ERISA, *id.* §1024(a)(2)(B), and authorizes the Secretary "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(a)(1).

In enacting ERISA, Congress recognized that "employers establishing and maintaining employee benefit plans are faced with the task of coordinating complex administrative activities" and that "[a] patchwork scheme of regulation would introduce considerable inefficiencies in benefit program operation." *Fort Halifax Packing Co.* v. *Coyne*, 482 U.S. 1, 11 (1987). Congress thus provided in ERISA's preemption provision, 29 U.S.C. §1144(a), that ERISA "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" covered by the federal law. This Court has "observed repeatedly that this broadly worded provision is 'clearly expansive.'" *Egelhoff* v. *Egelhoff*, 532 U.S. 141, 146 (2001). It ensures that plans are not subject to potentially conflicting regulations in 50 States (in addition to federal ERISA regulations) and that plan resources are, to the extent possible, devoted to the provision of benefits rather than administrative costs.

ERISA also exempts limited kinds of state laws from preemption. ERISA's savings clause, 29 U.S.C. §1144(b)(2)(A), generally exempts from preemption "any law of any State which regulates insurance, banking, or securities." ERISA's "deemer" clause, *id.* §1144(b)(2)(B), limits that exemption, however, by providing that "an employee benefit plan governed by ERISA shall not be 'deemed' an insurance company, an insurer, or engaged in the business of insurance for purposes of state laws 'purporting to regulate' insurance companies or insurance contracts." *FMC Corp.* v. *Holliday*, 498 U.S. 52, 58 (1990). The deemer clause reinforces the preemption provision and ensures that States may not assert authority over self-insured ERISA plans under the guise of their traditional regulation of health insurance. *See id.* at 61.[2]

B. Vermont's Reporting Requirements

1. The Database Statute

This case involves steps that Vermont has taken to bring self-insured ERISA medical plans within the State's regulatory ambit, notwithstanding Congress's express provision that such plans should be subject only to uniform federal regulations. Vermont enacted 18 V.S.A. §9410 (the Database Statute), which requires the creation of a "unified health care database." *Id.*

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[2] Self-insured (or self-funded) plans pay benefits directly out of plan resources, rather than purchasing insurance. The Court has recognized the important distinction between the two kinds of plans and has stressed that self-insured plans are largely immune from state regulation. *See FMC*, 498 U.S. at 61-63. ERISA plans that purchase insurance from an insurance company (fully insured plans) remain indirectly subject to state insurance regulation, insofar as the state insurance regulations apply to the plan's insurer. *Id.* at 61.

§9410(a)(1). The Database Statute requires "[h]ealth insurers, health care providers, health care facilities, and governmental agencies" to file those "reports, data, schedules, statistics, or other information determined … to be necessary to carry out the purposes" of the statute. *Id.* §9410(c). Although the Database Statute uses the term "health insurers" to define its scope, it is not limited to traditional health insurance companies. "Health insurer" is defined to include

> 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.

Id. §9410(j)(1)(B) (emphasis added). The administrator of a self-insured plan, as well as any third-party administrator with which the administrator contracts, falls within that definition.

Under the Database Statute, information that must be reported "may include: (1) health insurance claims and enrollment information used by health insurers." 18 V.S.A. §9410(c)(1). "Health insurers" must report

> (A) their health insurance claims data, provided that the [Green Mountain Care] 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.

Id. §9410(h)(1). Although, as discussed below, the regulation that implements the Database Statute does not require collection of data on *denied* claims, the Database Statute does not contain any such limitation and apparently authorizes the implementing agency to seek information about denied claims, and much other information besides.

Information collected under the Database Statute is to be broadly disseminated. "To the extent allowed by [the federal Health Insurance Portability and Accountability Act (HIPAA)]," data collected shall be available to third parties: "[T]he data shall be available as a resource for insurers, employers, providers, purchasers of health care, and State agencies." 18 V.S.A. §9410(h)(3)(B). That data is supposed to be anonymized, however. *See id.* §9410(h)(3)(D).

2. The implementing regulation

Regulation-H-2008-01 implements the Database Statute and creates the Vermont Healthcare Claims Uniform Reporting and Evaluation System (VHCURES). The Regulation imposes specific reporting requirements on entities covered by the Database Statute. Under the Regulation, "health insurers" are subject to annual registration requirements and must "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." *Id.* §4(A). Section 3(X) defines "health insurer" to include "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." Section 3(X) further provides that the term "health insurer" also includes, "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."

Under the Regulation, "[h]ealth [i]nsurers shall regularly submit medical claims data, pharmacy claims data, member eligibility data, provider data, and other information" in accordance with the regulation's data submission requirements. Regulation H-2008-01, §4(D). (The Regulation elsewhere excludes denied claims from the submission requirement. *Id.* §5(A)(8).) The data submission requirements regulate, among other things, the content, coding, encryption, and file format of the data. *Id.* §5(A). The Regulation also includes detailed file specifications that dictate such minutiae as the placement of decimal points and the justification of text fields. *Id.* §5(B). Data must be submitted on a prescribed schedule, which varies from monthly to quarterly to annually, depending on the number of members living or receiving services in Vermont. *Id.* §6(I). Health insurers with fewer than 200 enrolled or covered members living or receiving services in Vermont are considered voluntary reporters and may, but are not required to, submit data for use in the database. *Id.* §§3(Ab), 3(As), 4(E), 6(I).

C. Liberty Mutual's Self-Insured Employee Medical Plan

Liberty Mutual Insurance Company is the administrator and named fiduciary of a welfare benefit plan (Plan) that Liberty Mutual established for the benefit of company employees. The Plan provides medical benefits to more than 30,000 employees of Liberty Mutual Group Inc. and its subsidiaries, as well as those employees' families and company retirees. As of June 30, 2011, the Plan provided medical benefits to 84,711 persons located in all 50 States. Pet. App. 50.

The Plan is self-funded, or self-insured, as Liberty Mutual pays all benefits provided under the Plan from its own assets. Pet. App. 50. Liberty Mutual uses a third-party administrator (TPA), Blue Cross Blue Shield of Massachusetts, Inc. ("Blue Cross") to handle processing, reviewing, and paying claims for Vermont participants in the Plan. *Id.* 8.

The Plan's governing documents provide that the "'Plan has been established for the exclusive benefit of Participants'" and that "'all contributions under the Plan may be used only for such purpose.'" Pet. App. 8. The Plan also represents that specified medical information that participants provide will be kept "'strictly confidential.'" *Id.* In addition, the contract between Liberty Mutual and Blue Cross requires Blue Cross to use information it receives from Liberty Mutual solely for purposes of administering the Plan and includes requirements directed at guarding against unauthorized disclosure of the information. *Id.* 51.

Both Liberty Mutual and Blue Cross are considered "health insurers" subject to Vermont's reporting requirements. Although Liberty Mutual has fewer than 200 participants or beneficiaries in Vermont and is

thus a voluntary reporter, Blue Cross is a mandatory reporter and must therefore report, for participants in the Plan, claims data in its possession. Pet. App. 54.

D. Proceedings Below

In 2011, Blue Cross received a subpoena demanding Liberty Mutual's medical and pharmacy claims files for use in Vermont's health care database. JA30-33. Liberty Mutual directed Blue Cross not to comply with the subpoena and filed a complaint in federal district court, seeking a declaration that ERISA preempts Vermont's reporting regime, to the extent it requires the reporting of claims information about participants in self-insured plans, and an injunction against enforcement of the subpoena. Pet. App. 9.

The district court ruled that Vermont's law and regulations are not preempted by ERISA. Pet. App. 61-79. A divided panel of the court of appeals reversed, and held that ERISA preempts Vermont's reporting requirements insofar as it requires the reporting of claims information about participants in self-insured plans. *Id.* 1-47.

For guidance, the court of appeals looked to this Court's test for ERISA preemption set forth in *Shaw* v. *Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983): "[A] state law is preempted if 'it [1] has a connection with or [2] reference to [an ERISA] plan.'" Pet. App. 14 (emphasis omitted). The court observed that, in *Shaw*, this 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.* (quoting *Shaw*, 463 U.S. at 98). And, the court explained, recent precedents have not changed two constants: "(1) recognition that ERISA's preemp-

tion clause is intended to avoid a multiplicity of burdensome state requirements for ERISA plan administration; and (2) acknowledgement that 'reporting' is a core ERISA administrative function." *Id.* 3-4.

Applying those principles, the court concluded that Vermont's reporting requirements are preempted as applied to ERISA plans because those requirements have a "'connection with' ERISA plans." Pet. App. 23. The court relied on the principle that "'reporting' is a core ERISA function shielded from potentially inconsistent and burdensome state regulation." *Id.* The court acknowledged that "[n]ot every state law imposing a reporting requirement is preempted" and that ERISA tolerates "laws that create no impediment to an employer's adoption of a uniform benefit administration scheme and with too tenuous, remote, or peripheral an effect on employee benefit plans." *Id.* 24 (internal quotation marks, citations and brackets omitted). But, the court stressed, Vermont requires the reporting of "information about the essential functioning of employee health plans." *Id.* 29 n.13.

The court also found preemption here to be necessary "to avoid proliferation of state administrative regimes" that would subject the Plan to overlapping and potentially conflicting requirements. Pet. App. 21. The court explained that "[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." *Id.* 24 n.11. It thus concluded that the burden of Vermont's reporting requirements, when "considered as one of several or a score of uncoordinated state reporting regimes," was "obviously intolerable." *Id.* 25.

SUMMARY OF ARGUMENT

Vermont's laws are preempted because they have "a connection with" employee benefit plans. They require plans to report on activity that is at the core of what plans do—provide benefits.

I. A central objective of ERISA is to provide a uniform regulatory regime over plans, thereby minimizing the administrative burdens imposed on them and maximizing plan resources available to pay benefits. ERISA therefore includes an expansive preemption provision intended to ensure that plan regulation is exclusively federal. Reporting requirements are a key piece of ERISA's uniform regulatory regime.

The evolution of ERISA shows that Congress was acutely concerned that States would undermine the federal regime's uniformity and plan efficiency by imposing additional reporting requirements. Congress intended ERISA to relieve plans of the burden of multiple reporting obligations, forbidding States from requiring plans to report about the claims they pay.

II. Vermont's reporting requirements, as applied to ERISA plans, are fundamentally inconsistent with ERISA's objectives in at least three ways.

A. Vermont's requirements implicate an area of core ERISA concern: claims paid under an employee benefit plan. The obligation to report claims data arises from self-insured plans engaging in an essential plan function—providing medical benefits to participants. Vermont's regime is tied directly to a core function of an ERISA plan, distinguishing it from reporting obligations attendant to generally applicable state laws that are not directed at the core act of providing health care benefits. Vermont's law is therefore preempted, re-

gardless of whether the federal government currently requires disclosure of the same information.

B. Reporting requirements like Vermont's interfere with nationally uniform plan administration because they impose state-prescribed recordkeeping and reporting obligations that plans do not face in other States and that have not been imposed by the federal government. Those requirements depart from federal reporting requirements in terms of content, timing, and formatting, and they also differ widely across States. Congress, however, intended ERISA to protect plans from having to comply with 50 state reporting regimes.

C. Vermont's reporting requirements prevent the plan fiduciary from administering the plan in accordance with plan documents because they conflict with obligations the plan documents impose upon the Plan.

III. Preemption of Vermont's reporting requirements is not inconsistent with the objectives of federal statutes enacted after ERISA, nor are those statutes relevant to determining ERISA's purpose. Nor can Vermont's reporting requirements escape ERISA's reach as a generally applicable state health care regulation. The requirements target health care payers, not health care providers, and are very different from the types of state health care regulations that this Court has previously held to be free from ERISA preemption.

ARGUMENT

ERISA contains perhaps the broadest preemption provision in the United States Code. The federal law "supersede[s] any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. §1144. That clause reflects a congressional intent that state laws must yield to ERISA if

they have "a connection with" ERISA plans, determined by looking "both to 'the objectives of the ERISA statutes as a guide to the scope of the state law that Congress understood would survive,' as well as to the nature of the effect of the state law on ERISA plans." *Egelhoff*, 532 U.S. at 147. Whatever might be said about the outer limits of "connection," that concept is satisfied in this case. ERISA preempts Vermont's attempt to bring self-insured benefit plans within its reporting regime.

Although petitioner seeks to paint Vermont's reporting requirements as tangential to Congress's concerns in ERISA, in fact one of Congress's principal objectives was to ensure that benefit plans would not have to face multiple, potentially conflicting, reporting requirements about payment of benefits. The preemption language in the disclosure law ERISA repealed was exceedingly narrow, expressly allowing States to supplement minimum federal reporting requirements with their own. ERISA's preemption language, in contrast, is exceedingly broad. And one of the most striking things about the evolution of ERISA in the legislative process was just how concerned Congress was with establishing a uniform federal reporting regime. Congress no longer wanted federal law to be a source of minimum reporting standards; it intended federal law to be the source of uniform standards. Congress enacted ERISA's broad preemption provision in part to make its federal reporting requirements exclusive.

Vermont's reporting requirements concern the core of what ERISA plans do. Vermont demands information about benefits that Liberty Mutual has paid under its employee welfare benefit plan. But providing benefits is what ERISA plans do every day; that is what makes them ERISA plans. Vermont's reporting

regime is not a generally applicable law concerning matters merely incidental to the provision of benefits.

Congress intended ERISA to establish a uniform regulatory regime that would allow self-insured plans to operate free from the burdens of state reporting obligations like the ones imposed by Vermont. Vermont's requirements directly implicate a core plan function (the payment of benefits under the Plan), interfere with nationally uniform plan administration, and conflict with the Plan's terms. The Vermont requirements are therefore preempted.

I. ERISA Preempts State Mandates To Report About Core ERISA Subject Matters

A. Congress Intended ERISA To Benefit Plan Participants And Beneficiaries By Minimizing Administrative Burdens Through A Uniform Federal Regulatory Regime

The parties agree that "[t]he principal object of [ERISA] is to protect plan participants and beneficiaries." *Boggs*, 520 U.S. at 845. How ERISA accomplishes that objective, however, is a complex matter, and petitioner presents a decidedly one-sided and incomplete picture. In part, ERISA protects plan participants and beneficiaries by imposing strong federal requirements to prevent the mismanagement of funds and the failure to pay benefits. But Congress also recognized that employees and beneficiaries would not benefit from plans that operated in an inefficient way, encumbered by costly administrative requirements. Congress did not want "a system that is so complex that administrative costs … unduly discourage employers from offering welfare benefit plans in the first place." *Varity Corp.* v. *Howe*, 516 U.S. 489, 497 (1996).

Preemption of state law was central to Congress's objective of ensuring that plans operate efficiently. Congress wanted plan resources to be available for payment of benefits rather than administrative costs. Congress also wanted benefit plans to be free to operate nationally, without needing to comply with potentially conflicting state insurance regulation. "The purpose of ERISA is to provide a uniform regulatory regime over employee benefit plans." *Aetna Health Inc.* v. *Davila*, 542 U.S. 200, 208 (2004). The preemption clause is intended "to minimize the administrative and financial burden of complying with conflicting directives among States or between States and the Federal Government. Otherwise, the inefficiencies created could work to the detriment of plan beneficiaries." *Ingersoll-Rand Co.* v. *McClendon*, 498 U.S. 133, 142 (1990). Administrative costs, after all, are "ultimately borne by the beneficiaries." *Egelhoff*, 532 U.S. at 150.

Congress also enacted uniform requirements to encourage employers to establish employee benefit plans in the first place. This Court has repeatedly recognized that "ERISA 'induc[es] employers to offer benefits'" by assuring them a uniform set of regulations. *Conkright* v. *Frommert*, 559 U.S. 506, 517 (2010). Absent preemption, Congress understood, employers might be so deterred by the administrative burden and cost of complying with multiple state regulations that they might not set up an employee benefit plan at all.

B. ERISA's Uniform Regulatory Regime Includes Reporting

A major premise of petitioner's argument (joined by the United States) is that—notwithstanding this Court's repeated references to reporting and disclosure as core aspects of ERISA's uniform regulatory re-

gime—Congress was concerned with uniformity only as to fiduciary standards, substantive eligibility for plan benefits, and the mechanisms by which benefits are disbursed. Thus, petitioner argues, reporting about claims is tangential to ERISA, and the States are free to impose their own reporting requirements, even if those requirements are different from those imposed by the federal government (and different from State to State).

That argument is misguided. Congress made uniform reporting a key piece of ERISA's national regulatory regime. "Reporting and Disclosure" is the first of seven titular parts encompassing ERISA's "Regulatory Provisions." ERISA §§101-111, *codified as amended at* 29 U.S.C. §§1021-1031. The federal reporting requirements promulgated under ERISA, 29 C.F.R. Part 2520, are extensive.

This Court has repeatedly recognized that reporting by employee benefit plans is a core subject matter covered by ERISA. *See California Div. of Labor Standards Enforcement* v. *Dillingham Constr., N.A.*, 519 U.S. 316, 330 (1997); *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.*, 514 U.S. 645, 661 (1995); *Ingersoll-Rand*, 498 U.S. at 137; *FMC*, 498 U.S. at 58; *Fort Halifax*, 482 U.S. at 9; *Shaw*, 463 U.S. at 97. And the Court has stated repeatedly that ERISA's preemption provision encompasses state regulation of reporting by employee benefit plans. *See, e.g.*, *Travelers*, 514 U.S. at 661; *FMC*, 498 U.S. at 58; *Shaw*, 463 U.S. at 98; *see also Fort Halifax*, 482 U.S. at 9 (suggesting that state regulations that required plans "to keep certain records in some States but not in others" would be preempted).

Petitioner and the United States suggest that this Court's language has been overinclusive, and that the only purpose Congress had for ERISA's reporting regime was to serve the related goals of preventing the mismanagement of funds and failure to pay benefits. Pet. Br. 36-38; U.S. Br. 15-16. But this Court's language has been precise and accurate. As explained below, Congress was concerned that States would undermine the uniformity of the regime governing ERISA plan functions and the efficiency of ERISA plans by imposing additional, potentially burdensome reporting requirements. For that reason, Congress preempted state laws that require *reporting* about benefits—not just state laws that regulate the benefits themselves.

C. Congress Intended To Preempt State Mandates To Report About ERISA Subjects, Including Claims

Federal legislation before ERISA established minimum, but not exclusive, reporting requirements for employee benefit plans. Congress began regulating employee benefit plans with the Welfare and Pensions Plans Disclosure Act (WPPDA), Pub. L. No. 85-836, 72 Stat. 997 (1958). *See Malone* v. *White Motor Corp.*, 435 U.S. 497, 506 (1978). That law established federal reporting standards—requiring plan administrators to annually report information such as "the number of employees covered" and "the amount of benefits paid or otherwise furnished," WPPDA §7(b), 72 Stat. 1000—but allowed States to supplement federal reporting requirements. Although the WPPDA shielded employers from duplicative *identical* state and federal reporting requirements, it included an anti-preemption clause stating that the federal requirements *did not* "prevent

any State from obtaining such additional information relating to any such plan as it may desire, or from otherwise regulating such plan." *Malone*, 435 U.S. at 505 (quoting WPPDA §10(a), 72 Stat. 1003).

Congress "came to quite a different conclusion in 1974 when ERISA was adopted." *Malone*, 435 U.S. at 512. ERISA repealed the WPPDA. *Id.* at 505 n.7. Congress's experience with benefit plans led it to conclude that a uniform federal law was essential to ensure that plans would operate efficiently, with resources inuring to the benefit of employees and beneficiaries rather than being drained for administrative costs. Congress's view about preemption evolved during the legislative process, but one thing never in doubt was that plans should be relieved of the burden of multiple reporting obligations.

ERISA's broad preemption provision originated as a narrower but more detailed provision specifically targeting state reporting requirements. As introduced in the House, the bill that became ERISA would have preempted state laws "relat[ing] to the fiduciary, *reporting, and disclosure responsibilities* of persons acting on behalf of employee benefit plans." *FMC*, 498 U.S. at 59 n.3 (quoting H.R. 2, 93d Cong., 1st Sess., §514(a) (1973) (emphasis added)). The House approved the bill in slightly modified form, preempting state laws "relat[ing] to *the reporting and disclosure responsibilities*, and fiduciary responsibilities, of persons acting on behalf of any employee benefit plan." *Shaw*, 463 U.S. at 98 n.18 (quoting H.R. 2, 93d Cong., 2d Sess., §514(a) (1973)).

The bill that was introduced in and passed the Senate did not expressly refer to "reporting," but it preempted state laws "relat[ing] to the subject matters

regulated by" the bill, *FMC*, 498 U.S. at 59 n.3 (quoting S. 4, 93d Cong., 1st Sess. §609(a) (1973)), and reporting was a regulated subject matter. The Senate committee report endorsing the bill, like the corresponding House committee report, made clear that the bill was intended to preempt state reporting laws. S. Rep. No. 93-127, at 35 (1973) ("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)); *see also* H.R. Rep. No. 93-533, at 17 (1974).

The Conference Committee replaced the House's reporting-specific preemption provision with the preemption provision in the current statute, thus adopting "significantly broadened" language, *Metropolitan Life Ins. Co.* v. *Massachusetts*, 471 U.S. 724, 745 (1985), with a broader preemption purpose, *FMC*, 498 U.S. at 58-59. This broader goal necessarily encompassed the more specific objective to preempt state reporting laws. As one Conference Committee member summarized: "In view of Federal preemption, State laws compelling disclosure from private welfare or pension plans … will be superseded." 120 Cong. Rec. 29,942 (1974) (Sen. Javits).

The broad preemption provision was central to Congress's core objectives in ERISA, for it protected plans—and ultimately, plan participants and beneficiaries—from burdensome state requirements. Following the Conference, ERISA's principal House sponsor explained that preemption was "to many the crowning achievement of this legislation…. With the preemption of the field, we round out the protection afforded par-

ticipants by eliminating the threat of conflicting and inconsistent State and local regulation." *Shaw*, 463 U.S. at 99 (quoting 120 Cong. Rec. 29,197 (1974) (Rep. Dent)); *accord id.* (quoting 120 Cong. Rec. 29,933 (1974) (Sen. Williams)).

Preemption of state reporting requirements was essential to enactment of ERISA. Employee benefit plan reform resulted from a compromise in which business and labor interests accepted strong federal reporting and fiduciary standards in exchange for those federal standards being exclusive.[3] Preemption of state reporting requirements was always understood as a necessary part of the bargain. Beginning with the Nixon Administration's first proposal, which ultimately led to ERISA, *see Metropolitan Life*, 471 U.S. at 745 n.23, proposed employee benefits legislation had consistently included preemption of state reporting requirements. *See* S. 3589, 91st Cong., 2d Sess., §14, *in* 116 Cong. Rec. 7,284 (1970); *see also* 116 Cong. Rec. 7,286 (1970) (explanatory statement of Secretary of Labor) (bill provides for "a singular reporting and disclosure system in lieu of burdensome multiple reports"). Stakeholders emphasized the importance of uniform reporting requirements during the legislative hearings.[4]

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[3] *See* Wooten, *A Legislative and Political History of ERISA Preemption, Part 3*, 15 J. Pension Benefits 15, 19 (2008).

[4] *E.g.*, House Committee on Ways and Means, Written Comments Submitted by Interest Organizations and Individuals (Oct. 1, 1973) (C.R. Morgan) ("[L]egislation should provide a preemption of State law by the Federal law. The rapid expansion of conflicting State laws is creating an administrative jungle which requires a coordination of reporting requirements."), *in* 7 Legislative History of Employee Benefit Security Act, P.L. 93-406 [ERISA] (compiled by Covington & Burling LLP), at 783 (1974) ("Legislative History"); Senate Subcommittee on Private Pension Plans, Hearings on

Indeed, Members of Congress centrally involved in passing ERISA were acutely concerned about the administrative burden of *federal* reporting requirements.[5] They worried that the administrative burden of dual reporting to two *federal* agencies, the Treasury and Labor Departments, would ultimately harm plan beneficiaries.[6] The Secretary of the Treasury and Secretary of Labor agreed. They informed Congress that it was "essential to minimize the burdens placed on plan administrators by the numerous reporting requirements established under either the House or Senate bills" and recommended "consolidat[ing] all reporting require-

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Private Pension Plan Reform (June 4, 1973) (M.D. Furman) ("[C]ompliance with federal disclosure act reporting … should preempt state law…. It seems far better to spend these funds on benefits rather than on the support of company pension plan administrators, state insurance and banking department employee administrators."), *in* 6 Legislative History 1162.

[5] *E.g.*, House Subcommittee on Labor, Hearings on Welfare and Pension Plan Legislation (Feb. 21, 1973) (Rep. Dent) ("I am going to be anxious to hear anything that will cut down on the burdensome job of reporting."), *in* 5 Legislative History 94; House Subcommittee on Labor, Hearings on Welfare and Pension Plan Legislation (Apr. 27, 1973) (Rep. Burton) ("We're troubled about the excessive reporting requirements."), *in* 5 Legislative History 689.

[6] *E.g.*, 120 Cong. Rec. 4,778 (1974) (Rep. Price) ("Some estimates indicate that for many small companies the administration costs will double, and those costs are already running up as high as 40 percent of the overall costs of the plans in some cases. Dual reporting could literally force some of these small company plans out of existence[.]"); 120 Cong. Rec. 4,442 (1974) (Rep. Archer) ("I do take issue with the question of the cost to the employer which in effect becomes the cost of the worker for administration. If we have in effect provided all of these fine safeguards but the cost of providing reports in complying with all of the regulations of two Federal agencies, which might and probably will be conflicting, then we have undone all the good safeguards.").

ments into a single report" that was "simple and efficient from the standpoint of plan administrators." Administration Recommendations to the House and Senate Conferees on H.R. 2 (Apr. 1974), *in* 3 Legislative History of the Employee Retirement Income Security Act of 1974 (Committee Print prepared by the Senate Subcommittee on Labor), at 5127-5128 (1976); *see also id.* at 5131 (noting that uniform "form and detail" requirements, prescribed by one agency, were necessary to create "order in the reporting area, from the viewpoints of both the Labor Department and plan administrators").

The legislation, as ultimately enacted, responded to those concerns by directing federal agencies to avoid duplicative reporting requirements. *See* 29 U.S.C. §1204(a) (Treasury and Labor Departments "shall develop rules, regulations, practices, and forms which … are designed to reduce duplication of effort, *duplication of reporting*, conflicting or overlapping requirements, *and the burden of compliance with such provisions by plan administrators, employers, participants and beneficiaries*" (emphasis added)). The Conference Report explained that the federal government was to reduce duplication and the burden of compliance "to the maximum extent practical." H.R. Conf. Rep. No. 93-1280, at 360 (1974).

Given Congress's mandate that the federal government reduce the burden on plans of complying with just two federal agencies' reporting requirements, it is inconceivable that Congress would have allowed each of the 50 States to impose its own reporting requirements as well. Congress would not have prohibited duplicative reporting by the Treasury and Labor Departments only to allow States to thwart that prohibition through their own reporting requirements.

Moreover, Congress clearly understood that reporting about claims, like other reporting about core plan functions, could impose serious administrative burdens on plans. Congress was familiar with mandates to report information about claims from the WPPDA, which required plan administrators to file an annual report containing information including "the number of employees covered" and "the amount of benefits paid or otherwise furnished" for the year. WPPDA §7(b), 72 Stat. 1000. The original House and Senate bills that became ERISA would have likewise required plan administrators to annually report "the number of employees covered" and "the amount of benefits paid or otherwise furnished." H.R. 2, 93d Cong., 1st Sess., §104(b)(1); S. 4, 93d Cong., 1st Sess. §506(d). Concerned about administrative burden, Congress ultimately amended the bills to reduce their reporting requirements, choosing not to require plan administrators to report the amount of benefits paid. But Congress did require plans that use third-party insurance rather than self-insuring to report the total amount of claims paid by the insurer. *See* 29 U.S.C. §1023(e)(2).

The evolution of ERISA refutes petitioner's contention that Congress was unconcerned about claims reporting when it preempted state laws. To the contrary, Congress clearly considered claims information to be part of the reporting encompassed within ERISA and knew how to require claims reporting when it wanted to require that data. Congress also understood that reporting about claims could be extremely burdensome on plans, and it made the considered decision to relieve plans of the burden of filing duplicative—much less multiplicative—reports on that subject. Given Congress's detailed attention to claims reporting, it cannot be seriously maintained that reporting about

claims paid by an employee benefit plan is anything other than a core function of that plan. ERISA's preemption clause therefore forbids States from requiring ERISA plans to report about the claims that they pay.

II. VERMONT'S REPORTING REQUIREMENTS INTERFERE WITH CONGRESS'S DESIGN OF UNIFORM REGULATION IN AN AREA OF CORE ERISA CONCERN

Congress's central concern in enacting ERISA's preemption clause was ensuring that plans could operate nationally, efficiently, and for the benefit of employees and beneficiaries without the burden and expense of complying with multiple, potentially conflicting state law requirements. Vermont's reporting regime, as applied to ERISA plans, is inconsistent with that congressional design. *First*, Vermont's reporting requirements implicate an area of core ERISA concern: benefits paid under an employee benefit plan. *Second*, the requirements interfere with nationally uniform plan administration, considered by themselves or as part of the burgeoning set of disparate reporting obligations being mandated by the States. *Third*, they prevent the plan fiduciary from administering the plan in accordance with the plan documents.

A. Vermont's Reporting Requirements Implicate A Core Subject Matter Covered By ERISA

1. Vermont requires reporting about the core functions of self-insured ERISA plans

Vermont's reporting requirements are directly connected to an activity that is the essence of an employee welfare benefit plan under ERISA: self-insured plans' provision of health care benefits to their employ-

ees. That characteristic of Vermont's requirements distinguishes them from other state laws that may impose reporting requirements on ERISA plans but are not subject to preemption under ERISA.

a. The provision of employee benefits is a defining characteristic of an ERISA plan. ERISA defines an employee welfare benefit plan to include "any plan, fund, or program … [that provides] its participants or their beneficiaries, through the purchase of insurance or otherwise, … medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, [or] death." 29 U.S.C. §1002(1). Courts regularly look to the circumstances surrounding an employer's provision of benefits to its employees to determine whether an employee benefit plan has been established under ERISA. *E.g.*, *Okun* v. *Montefiore Med. Ctr.*, 793 F.3d 277, 279 (2d Cir. 2015).

Here, data from employee benefit plans become subject to Vermont's reporting requirements because those plans are engaging in their essential function of paying benefits. Vermont's reporting regime applies to "entities that pay for health care services provided to Vermont residents" (Pet. Br. 10) and requires those entities to provide "claims data." The regime clearly targets plans' provision of health benefits to plan members and is directly tied to that core plan function. Under these circumstances—where a State requires reporting because a self-insured employee health plan is engaged in the very activity that defines it as a self-insured employee health plan—the state law necessarily has a connection with the plan and is preempted.

b. Petitioner seeks to avoid preemption here by listing the various kinds of data that it presently does *not* include within its reporting requirements, such as

information on denied claims. Pet. Br. 44. But Vermont does not disclaim the authority to apply its regime more broadly, to encompass denied claims as well as a great deal of other information about plan benefits, and the wording of the Database Statute suggests it may ultimately do so. The statute is sweeping; it requires covered entities to report their "health insurance claims data," not merely information about paid claims. *See* 18 V.S.A §9410(h)(1)(A); *see also id.* §9410(c)(1) (requiring reporting of "health insurance claims and enrollment information used by health insurers"). Although Vermont regulators for the moment have decided not to request information about denied claims, nothing in the Database Statute prevents them from seeking that information in the future. And other States that are developing similar databases do require information on denied claims. *See infra* pp. 35-36.

In any event, what Vermont *has* required—the reporting of data on claims paid under self-insured plans—is directly connected to the core activities of an ERISA plan. Because it is the payment of health benefits—a core function of a self-insured employee health plan—that leads to the requirement to report claims data to Vermont, the connection required for ERISA preemption is plainly present.

2. Vermont's reporting law is preempted even though the federal government does not currently require disclosure of the same information

Petitioner and the United States argue that ERISA does not preempt Vermont's reporting regime because the reporting requirements in Vermont's law and in ERISA serve different purposes. Pet. Br. 36-39;

U.S. Br. 10-11, 15-19. They contend that the reporting requirements in ERISA were enacted to protect plan beneficiaries from fiduciary mismanagement and that Vermont's reporting regime does not relate to that purpose. That position suffers from severe flaws.

a. First, there is no basis to petitioner's and the United States' assumption that Congress intended to reserve for exclusive federal authority only those reporting requirements concerning fiduciary mismanagement. No such distinction appears in the text of ERISA, which recognizes the Secretary of Labor's broad authority to impose reporting requirements on plans, including requirements beyond what would be necessary to protect plan beneficiaries from fiduciary mismanagement. *See* 29 U.S.C. §1024(a)(2)(B) ("Nothing contained in this paragraph shall preclude the Secretary from requiring any information or data from any such plan to which this part applies where he finds such data or information is necessary to carry out the purposes of this subchapter").[7] And ERISA by its terms "supersede[s]" "any and all" state laws relating to employee benefit plans, not just state laws relating to the fiduciary aspects of plan management.

Moreover, the United States appears to take the position that it *does* have the power to impose claims

[7] In addition, under 29 U.S.C. §1143(a)(1), the Secretary has the authority "to undertake research and surveys and in connection therewith to collect, compile, analyze and publish data, information, and statistics relating to employee benefit plans." Further, some plans are subject to claims reporting requirements under ERISA; plans that purchase third-party insurance must report the total claims paid by the third-party insurer. *Id.* §1023(e)(2).

reporting requirements on self-insured ERISA plans.[8] At the petition stage, the United States represented that the Secretary of Labor—"in aid of his authority to ensure compliance with ERISA's fiduciary standards and claims processing rules"—"is currently considering undertaking a rulemaking to require health plans to report more detailed information about the cost of benefits, *utilization of medical services*, and plan administration." CVSG Br. 3 n.1 (emphasis added). The United States has reaffirmed its position in its merits brief, noting that the Secretary of Labor, "pursuant to the authority granted by ERISA and the [Affordable Care Act (ACA)], … is currently considering a rulemaking to require health plans to report more detailed information about various aspects of plan administration, such as enrollment, claims processing, and benefit offerings." U.S. Br. 4.

Although the contours of this proposed rulemaking remain unclear, at no point in this case—either before the court of appeals or before this Court—has the United States denied that the Labor Department would have the power under ERISA to impose on self-insured plans the exact same claims reporting requirements that Vermont has enacted.[9] And if—as the

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[8] Even if ERISA did not grant the Labor Department the authority to impose claims reporting requirements, then Congress's decision not to grant that authority, coupled with ERISA's preemption provision, would represent Congress's determination that ERISA plans should remain free from those kinds of requirements at both the federal and the state levels. *See Arkansas Elec. Coop. Corp.* v. *Arkansas Pub. Serv. Comm'n*, 461 U.S. 375, 383-384 (1983).

[9] The United States asserts that the ACA establishes new reporting requirements applicable to group health plans but that those requirements "would not fill the void left by invalidating

United States also does not deny—such federal reporting requirements, once enacted, *would* preempt additional state reporting requirements, then it is hard to see why those state requirements are not preempted now. ERISA preempts *all* state laws relating to employee benefit plans, not just state laws relating to plans once the Labor Department has enacted a regulation covering the same subject. Otherwise preemption could expand and contract like an accordion, depending on the policy preferences of the Labor Department at any particular time.

Nor does it matter that ERISA allows the Secretary of Labor to exempt welfare benefit plans from "all or part of the reporting and disclosure requirements" of the law or to require only simplified reporting from welfare plans, 29 U.S.C. §1024(3), and that the Secretary has exercised that authority for certain welfare plans, *see* U.S. Br. 2. The scope of ERISA's preemption of *state* reporting and disclosure requirements cannot turn on which *federal* reporting requirements the Labor Department has until now seen fit to enforce. The fact that the Labor Department has chosen to exempt certain plans from some of ERISA's reporting requirements does not mean that Congress intended for welfare benefit plans to be subject to 50 States' reporting laws. Indeed, the Labor Department's decision not to impose burdensome reporting requirements on certain employee welfare benefits plans is itself a regulatory choice that should not be upset by the application of state reporting requirements. *See Arkansas Elec.*

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state-level efforts to compile databases of healthcare-expenditure information across the board." U.S. Br. 21-22. The United States, however, does not disclaim the position that ERISA gives it the authority to require claims data from welfare benefit plans.

Coop. Corp. v. *Arkansas Pub. Serv. Comm'n*, 461 U.S. 375, 383-384 (1983).

Moreover, the position taken by petitioner and the United States is not compatible with this Court's recognition that preemption is not limited to state laws specifically dealing with the subject matters covered by ERISA. ERISA does not need to speak specifically to a subject for a state law addressing that subject to "relate to" an employee benefit plan under §1144(a). *See FMC*, 498 U.S. at 58-59 (observing that interpreting the preemption clause "to apply only to state laws dealing with the subject matters covered by ERISA" would be incompatible with Congress's intent); *cf. Shaw*, 463 U.S. at 96-97 (holding that a state anti-discrimination statute "relates to" an employee benefit plan even though ERISA "does not mandate that employers provide any particular benefits, and does not itself proscribe discrimination in the provision of employee benefits"). Congress intended ERISA plans to be subject to one set of regulations, and state intrusion into this area is prohibited even if state regulation does not require something the federal government forbids, or vice versa.

b. More generally, petitioner and the United States err by attempting to distinguish between the purpose of the state law and the federal regulations. A state law—even one with a noble purpose—is preempted if its *effects* conflict with Congress's objectives in ERISA. A state law does not avoid preemption simply because it was enacted for a purpose different from the purposes underlying ERISA's requirements.

This Court's broader preemption jurisprudence makes this point clear. For example, the Court rejected the argument that the Occupational Safety and Health Act (OSHA) would lose its preemptive force if

"the state legislature articulates a purpose other than (or in addition to) workplace health and safety." *Gade* v. *National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 105 (1992). The Court noted that it would defeat the purpose of OSHA "if a state could enact measures stricter than OSHA's and largely accomplished through regulation of worker health and safety simply by asserting a non-occupational purpose for the legislation." *Id.* at 106. It concluded that, "[w]hatever the purpose or purposes of the state law, pre-emption analysis cannot ignore the effect of the challenged state action on the preempted field." *Id.* at 107; *see also id.* at 106 ("[P]reemption analysis turns not on whether federal and state laws 'are aimed at distinct and different evils' but whether they 'operate upon the same object.'"). Similarly, this Court has rejected the notion "that state law may frustrate the operation of federal law as long as the state legislature in passing its law had some purpose in mind other than frustration." *Perez* v. *Campbell*, 402 U.S. 637, 651 (1971).

The Court's observations in *Gade* and *Perez* illustrate why the position taken by petitioner and the United States is untenable. Vermont may have had a benign objective in deciding to construct a claims database, but the *effect* of the application of its Database Statute is to require the reporting of data about payment of claims—a core plan function—that Congress determined should be imposed by the federal government, or not at all. That forbidden effect is sufficient for preemption.

B. Vermont's Reporting Requirements Interfere With Nationally Uniform Plan Administration

1. State claims reporting requirements depart from federal standards and differ widely

a. ERISA preempts state laws that "interfere[] with nationally uniform plan administration." *Egelhoff*, 532 U.S. at 148. Vermont's reporting requirements interfere with uniform administration of employee benefit plans because they impose recordkeeping and reporting obligations on the plans that apply only to the plan's reporting of Vermont-related claims, obligations that the federal government has not imposed and that plans do not face in other States. *See id.* ("Uniformity is impossible … if plans are subject to different legal obligations in different States.").

The court of appeals catalogued several of those "myriad," "burdensome," "time-consuming" requirements. Pet. App. 25-27. They govern content, requiring extensive data about medical claims, pharmacy claims, member eligibility, and other information that differs from the data the federal government requires. *See* Regulation H-2008-01 §§4-5. They govern timing, requiring plans to report their data monthly, quarterly, or annually, even though ERISA contemplates only a single report annually. *Compare id.* §6 *with* 29 U.S.C. §1021.

Vermont's regulations also impose detailed coding and formatting obligations that have no federal parallel. *See* Regulation H-2008-01 §5. Petitioner's amici argue that Vermont's regulations impose "no new or unique recording-keeping" requirements for data beyond what HIPAA already requires. NAHDO Br. 5-11. But Vermont's regulations show otherwise. Their appen-

dices outline numerous data elements that Vermont requires for which there is no parallel HIPAA standard, including, among many others: Member Suffix or Sequence Number, Date Service Approved, Coinsurance Amount, Deductible Amount, Prepaid Amount, Co-pay Amount, Discharge Date, National Billing Provider ID, and encrypted information identifying the subscriber and member.[10]

Vermont's regulations thus require state-specific processing of records and reporting, obligating plans to provide state-prescribed information in a state-prescribed format and at state-prescribed intervals on state-specified claims paid by the plan. The requirements call for different information, at different intervals, and in a different format than the federal government requires. They contradict ERISA's objective that plans should not be "required to keep certain records in some States but not in others." *Fort Halifax*, 482 U.S. at 9. And their state-specific requirements preclude plans from accomplishing ERISA's overarching goal of establishing a nationally uniform administrative scheme.

Petitioner and the United States do not dispute that Vermont's reporting scheme obligates plans to process records for and report information about claims in Vermont that the plan is not obligated to do for other

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[10] *See* Regulation H-2008-01, Apps. C2, D2, & E2, *available at* http://www.dfr.vermont.gov/sites/default/files/REG-H-08-01.pdf (mapping Vermont's required data elements to national standards and denoting "N/A" where there is no applicable national standard); *see also* VHCURES Data Submission Guide 33, 41, 56 (July 2015), *available at* http://www.onpointhealthdata.org/clients/vhcures/docs/onpoint_vhcures_dsg_v20.pdf (providing descriptions of Vermont's required data elements "that lack a national standard altogether").

States. They nonetheless argue that Vermont's scheme is not preempted because any interference with uniform plan administration "does not intrude on any core ERISA function," Pet. Br. 45, or "prescribe binding rules for a central matter of plan administration," U.S. Br. 24. That argument is incorrect for the reasons explained above: Recording and reporting about claims paid is a core ERISA function—a central matter of plan administration. *See supra* pp. 25-31.

b. Moreover, Vermont's reporting regime cannot be considered in isolation. If Vermont is allowed to impose claims reporting requirements on a self-insured plan, then presumably every other State can do so as well, even though each State might decide to require different information, reported at different intervals, and submitted in different formats. But the danger of state regulation of ERISA plans that Congress foresaw was that each State might impose different requirements on nationally operating plans, and that plans would have to expend resources in complying with those varying requirements that would otherwise be available for benefits. *See Egelhoff*, 532 U.S. at 149-150 ("Requiring ERISA administrators to master the relevant laws of 50 states … would undermine the congressional goal of 'minimiz[ing] the administrative and financial burden[s]' on plan administrators—burdens ultimately borne by beneficiaries."). "Thus, where a 'patchwork scheme of regulation would introduce considerable inefficiencies in benefit program operation,' [this Court has] applied the pre-emption clause to ensure that benefit plans will be governed by only a single set of regulations." *FMC*, 498 U.S. at 60.

That danger is plainly present here. The burdens that plans face from meeting conflicting state reporting requirements are significant. Although all-payer claims

database (APCD) statutes are relatively new—the first were enacted barely a decade ago—18 States have already enacted statutes that mandate reporting of claims data. *See* N.Y. Br. 1 n.1; NGA Br. 8 n.9. As the court of appeals recognized, state data submission requirements vary significantly. Pet. App. 7.

APCD statutes vary in whether they require reporting of denied claims. Although petitioner emphasizes that Vermont currently requires only information on paid claims, Pet. Br. 11, Oregon requires reporting of denied claims and other "encounter[s]."[11] Massachusetts does not yet require reporting of wholly denied claims, but does require reporting of a denied procedure encompassed within a paid claim, and has announced that it will require reporting of wholly denied claims.[12] Arkansas law authorizes compulsory reporting of denied claims, but regulators have not yet imposed that requirement.[13] Connecticut also does not

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[11] Or. Admin. R. 409-025-0100(12); *see* Oregon Health Authority, Memorandum to Mandatory Reporters 3 (Feb. 1, 2015), *available at* http://www.oregon.gov/oha/OHPR/rulemaking/notices/409-025_Appendices%20A-G.pdf ("Each submission shall include final claims (paid, *denied*, or *encounter only*)[.]" (emphasis added)).

[12] 114.5 Mass. Code Regs. 21.03(3)(b)(1)(a); *see* Massachusetts Center for Health Information and Analysis (CHIA), Massachusetts APCD Medical Claim File Submission Guide 4-5 (Oct. 2014), *available at* http://www.chiamass.gov/assets/docs/p/apcd/submission-guides/apcd-medical-claim-file-submission-guide.pdf ("Wholly denied claims are not submitted to CHIA. However, if a single procedure is denied within a paid claim that denied line is reported."); *id.* at 10 (CHIA will provide notice "when the requirement to submit [wholly] denied claims will become effective").

[13] *Compare* Ark. Act 1233, Proposed Rule 100 §4(18) (reportable data includes "all paid and denied claims"), *available at* http://insurance.arkansas.gov/Legal/PropRules/PropRule100.pdf, *with* Arkansas APCD Data Submission Guide 3 (Sept. 18, 2015),

currently require reporting of denied claims but has not "rule[d] out a future change in such policy," despite recognizing that the "[c]omplexities surrounding the capture and interpretation of denied claims" are "very challenging."[14]

APCD statutes vary in the kinds of claims they require to be reported. Vermont and Rhode Island do not require reporting of dental claims, but the four other New England States do.[15] APCD statutes also vary in the kinds of information they require. Massachusetts, for example, requires information on plan premiums, actuarial assumptions underlying those premiums, summaries of plan designs, medical and administrative expenses, reserves and surpluses, and provider payment methods and levels.[16]

APCD statutes vary in when reporting is required. Some States, like Vermont, require reporting based on the number of persons covered (with varying numbers),[17] others do so based on total dollars of claims

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available at https://www.arkansasapcd.net/Docs/64 ("Denied claims are not required for the APCD at this time.").

[14] Connecticut Health Insurance Exchange, Report on Public Comments, Policies and Procedures 1 (Nov. 1, 2013), *available at* http://www.ct.gov/hix/lib/hix/APCD_Policies_and_Procedures_Public_Comment_Report.pdf.

[15] *Compare* Regulation H-2008-01, §4(D), *and* Rhode Island Department of Health, APCD Project, *available at* http://www.health.state.ri.us/partners/collaboratives/allpayerclaimsdatabase (last visited Oct. 13, 2015), *with* Conn. Gen. Stat. §38a-1091(a)(1); Me. Code R. tit. 90-590 ch. 243 §2(A), 114.5 Mass. Code Regs. 21.03(3)(b)(3), *and* N.H. Code Admin. R. Ins. 4006.03.

[16] 114.5 Mass. Code. Regs. 21.03(2)(a).

[17] Regulation H-2008-01, §3(Ab) (200 members); *e.g.*, Or. Admin. R. 409-025-0110(1)(a)(C) (5,000 lives); Utah Admin. Code R. 428-2-10(5) (2,500 residents).

paid,[18] and still others based on market share.[19] Some States require monthly reporting,[20] others quarterly,[21] and still others, like Vermont, require monthly, quarterly, or annually reporting depending on the number of state residents for which the reporter has claims.[22] And APCD statutes differ in how information must be reported. For example, in 2011, five States, including Vermont, were collecting direct patient identifiers, five States prohibited collection of direct patient identifiers, and still others allowed collection of that information but had not yet begun collecting it.[23] That variation persists: Currently, about half of state APCDs require data without patient identifiers for privacy and security purposes, but the other half require data with patient identifiers to allow researchers to link APCD data with clinical data analysis.[24]

These variations create substantial compliance burdens—exactly what ERISA prohibits. Plans must familiarize themselves with the reporting requirements in each State and report different content, on different

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[18] *E.g.*, Minn. R. 4653.0100(8) ($3,000,000 in annual claims).

[19] *See* APCD Council, APCD Development Manual 50 (Mar. 2015), *available at* https://www.apcdcouncil.org/manual (one percent market share in Kansas).

[20] *E.g.*, 114.5 Mass. Code Regs. 21.03(4)(b); Utah Admin. Code R. 428-15-3.

[21] *E.g.*, Md. Code Regs. tit. 10, §25.06.05.

[22] Regulation H-2008-01, §6(I); *e.g.*, Me. Code R. tit. 90-590 ch. 243, §3(F).

[23] APCD Council, APCDs 2.0: The Next Evolution 5 (July 2011), *available at* https://www.apcdcouncil.org/publication/apcd-20-next-evolution.

[24] APCD Council, APCD Development Manual 34.

schedules, in different formats. States also change what data they require and how they want it reported, setting out these requirements in elaborate regulations and separate data submission guides.[25] State data submission guides are not always even consistent with state regulations. Petitioner, for example, emphasizes that Vermont's regulations currently do not require reporting of denied items within a partially paid claim. *See* Regulation H-2008-01, §5(A)(8); *see also* JA129 (Vermont Frequently Asked Questions (FAQ) No. 4) ("[C]laims with mixed covered and non-covered services will include only the service lines for the covered services."). Vermont's submission guide, however, instructs: "All lines of partially denied claims are to be reported. Only fully denied claims are to be excluded." VHCURES Data Submission Guide 41.

Moreover, the same claim is often subject to multiple reporting requirements. When a claim has a nexus to more than one State—such as an employee who resides in one State, works in another State, and receives medical services in a third—plans may be required to report that same claim in different ways, at different times, to different States. *Cf. Egelhoff*, 532 U.S. at 149. Indeed, Vermont's reporting regime recognizes the reporting complications for companies that engage in interstate commerce and therefore have employees who may change state residence over time. *See* JA138-139 (Vermont FAQ No. 23).

Plans are therefore not just faced with dual reporting between two federal agencies, which ERISA discourages, or even between one State and the federal

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[25] *See, e.g.*, VHCURES Data Submission Guide 41, 45, 56, 59 (noting change in reporting data on a member's relationship to the insured).

government, which ERISA prohibits. They are currently faced with reporting to 18 States, a number certain to grow, further increasing administrative expenses. This checkerboard system of regulation is directly contrary to Congress's intent that ERISA plans should operate and be administered on a uniform national basis.

c. Some amici argue that state claims reporting requirements present no threat to national uniform plan administration because (they say) the reporting requirements are standardized and not burdensome. *E.g.*, NGA Br. 9-10, 14-15, 17-18; AHA Br. 20-21; NAHDO Br. 11-16. To the contrary, the state reporting laws on their face vary in terms of the content required, timing, and other procedures. *See supra* pp. 35-37. The materials amici cite also refute their own contentions.

Petitioner's amici point to materials drafted by amicus APCD Council, including a fact sheet on "Standardization of Data Collection in APCDs." *E.g.*, NGA Br. 9-11, 15 & n.26; AHA Br. 22; NAHDO Br. 13. That fact sheet, which is in the record,[26] makes clear that state reporting requirements are far from uniform. It recognizes that "currently each state is collecting different data by different methods and with different definitions. *This non-uniform approach to developing APCDs* is limiting the ability to share analysis and applications across states, and *is raising costs for payers submitting data to the states (especially those payers that are operating in multiple states)*." JA219 (emphasis added). It also recognizes that payers follow their own administrative schemes and that data submission is not standardized. JA220 ("Because payers each use

[26] The original is available at https://www.apcdcouncil.org/standards.

unique systems to administer their business, the challenges for payers to provide the required data vary."). It recognizes that payers must "allocate programming resources and funding" to comply with state reporting requirements and therefore need at least six months' notice to comply with any new ones. JA221. And it recognizes that the cost of complying will only continue to grow: "*As APCDs are required in more states, the cost to payers will become significant.*" JA220 (emphasis added).[27]

Amici suggest that state reporting requirements will become more uniform in the future because the APCD Council has proposed model legislation. *E.g.*, NGA Br. 10 & n.14, 18, 25-26; AHA Br. 9; NAHDO Br. 14. Even setting aside that ERISA does not permit a dual set of federal requirements and uniform state requirements, that point is unpersuasive; States are not bound to standardize reporting requirements or to enact model legislation. Preemption analysis does not turn on whether the States might converge on a uniform regime. To the contrary, if state laws are not preempted, then presumably the States are free to experiment with different approaches.

Moreover, the model legislation amici invoke is not actually intended to be uniform. The introduction to the APCD Council's model legislation acknowledges: "While the model legislation can be used by states to guide APCD development, it is important to note that legislation differs from state to state based on the needs of the state, the laws of the state, the politics at the time

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[27] The APCD Council's most recent publications continue to highlight the "technical and financial burden to the payers associated with data submission." APCD Council, APCD Development Manual 18.

of passage, and the policy basis for the data collection itself." APCD Council, Model APCD Legislation 2 (May 2015), *available at* https://www.apcdcouncil.org/publication/model-all-payer-claims-database-legislation. The model legislation is only "intended to offer guidance, and states will need to modify and supplement the template language in the model legislation to reflect the specific intent and design of the APCD program and to reflect existing state law…. Each state should consider the laws of its state and the needs of its own citizens, thereby adapting its legislation accordingly." *Id.*

If anything, the APCD Council's materials underscore that state reporting requirements threaten uniform federal regulation of ERISA plans. The APCD Council has proposed that States require premium and benefit information, including "co-payments, coinsurances, deductibles, out-of-pocket maximums, lifetime maximums, and detailed medical or pharmacy benefits." APCD Council, APCDs 2.0, at 7-9. And it has noted that already "[m]any states have explored the prospect of expanding the APCD beyond information captured from claims payment systems" to include "plan benefit design" and "premium information." APCD Council, APCD Development Manual 62. Massachusetts, for example, has enacted a regulation requiring "All Private Health Care Payers," including "self-insured plans," to provide information on premiums, actuarial assumptions, summaries of plan designs, medical and administrative expenses, reserves and surpluses, and provider payment methods and levels. 114.5 Mass. Code Regs. 21.03. ERISA, however, already requires plans to file a summary plan description, a self-insured plan's actuarial basis, the premiums the plan collects, and information on many other features of

self-insured plans. *See* 29 U.S.C. §§1021, 1022, 1023, 1024, 1026; 29 C.F.R. Part 2520.

The APCD materials show that, if Vermont's claims reporting requirements are upheld, nationally operating self-insured plans may have to meet numerous differing, even conflicting, state mandates. That result would be directly contrary to Congress's judgment that plans should not be subject to such administrative burdens and that reporting requirements are exclusively the federal government's realm.

2. Liberty Mutual was not required to quantify the cost of complying with Vermont's reporting mandate

Petitioner and the United States argue that Liberty Mutual has failed to show that Vermont's reporting requirements interfere with nationally uniform plan administration because it did not quantify the administrative cost of compliance. Pet. Br. 54-55; U.S. Br. 28-29. They are wrong. ERISA's objective was to "eliminat[e] the *threat* of conflicting or inconsistent State and local regulation." *Fort Halifax* , 482 U.S. at 9 (quoting 120 Cong. Rec. 29,933 (1974) (Sen. Williams)) (emphasis added); *see also Ingersoll-Rand*, 498 U.S. at 142 ("Particularly disruptive is the *potential* for conflict in substantive law." (emphasis added)). The "threat" that States could enact different reporting requirements suffices to establish preemption. *See Egelhoff*, 532 U.S. at 148.

This Court has never suggested, let alone held, that a plan must quantify the administrative costs imposed on it—and passed onto its participants and beneficiaries—to show that a state mandate interfered with uniform plan administration. *See Egelhoff*, 532 U.S. at 148-150; *Ingersoll-Rand*, 498 U.S. at 142. Nor has the

Court rested its judgments in favor of preemption on the specific cost of compliance with a state mandate. Moreover, the concern animating preemption is not just the burden imposed by Vermont's requirements but the potential burden that the Plan would face if it had to comply with as many as 50 potentially conflicting reporting requirements of a similar nature—a number that could not be quantified at this point. Liberty Mutual was not required to prove the cost of complying with Vermont's reporting mandate, nor to quantify the cost of complying with the 18 current state reporting mandates, nor to speculate about how much the cost of compliance will be if and when all 50 States impose reporting mandates.

Petitioner and the United States nevertheless suggest that Liberty Mutual had to prove that the burdens created by Vermont's reporting requirements were so acute "as to force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers." Pet. Br. 28 n.15 (quoting *De Buono* v. *NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 816 n.16 (1997)); U.S. Br. 27. That argument does not reflect a fair reading of the footnote in *De Buono*, which discussed the circumstances under which preemption might occur as a result of the indirect economic effects of a law that addressed an area *outside* ERISA's core subjects. The Court was not addressing the standard for preemption where, as here, a state law imposes direct administrative burdens on a core ERISA subject. Since *De Buono*, this Court has made clear that state laws imposing that effect are preempted because they threaten uniform plan administration. *Egelhoff*, 532 U.S. at 150. Vermont's reporting requirements have that impermissible effect.

C. Vermont's Mandates Conflict With ERISA's Requirement That A Plan Be Administered In Accordance With Plan Documents

1. ERISA also preempts Vermont's reporting requirements as applied to Liberty Mutual's self-insured plan because they interfere with the Plan's relationships with its members and its third-party administrator. The documents governing the Plan obligate it to keep many medical records strictly confidential. The Plan's agreement with its third-party administrator also requires that its members' medical information be used solely for the purpose of plan administration. The Plan has made those commitments to its members to ensure that their health information will be used only to the extent necessary to provide their health benefits under the plan.

By impairing those obligations, Vermont's reporting requirements conflict with ERISA's commands that a plan "shall" be administered "in accordance with the documents and instruments governing the plan." 29 U.S.C. §1104(a)(1)(D). Vermont makes the data it collects from ERISA plans "available as a resource for insurers, employers, providers, purchasers of health care, and state agencies." 18 V.S.A. §9410(h)(3)(B). Although the Vermont regime includes confidentiality protections, it nonetheless affects the documents governing Liberty Mutual's ERISA plan by "impair[ing] or (at least) reassign[ing] the obligation in the Plan documents to keep medical records strictly confidential, as well as the undertaking by Blue Cross as [third-party administrator] to use information solely for Plan administration purposes and to prevent unauthorized disclosure." Pet. App. 27. The Vermont requirements make it impossible for Liberty Mutual or Blue Cross to administer the Plan in accordance with the plan docu-

ments and are therefore preempted. *See Egelhoff*, 532 U.S. at 151.

2. The United States argues that the reporting requirement's impact on the documents governing the Plan is irrelevant. U.S. Br. 32-34. Its arguments lack merit.

First, the United States attempts to minimize *Egelhoff* by claiming that nothing in that decision "supports the view that a state law that is otherwise *not* preempted could be circumvented by a contrary term in a particular plan." U.S. Br. 33-34. But what made the statute in *Egelhoff* preempted was that the statute imposed a set of rules for determining beneficiary status that would have required administrators to pay benefits to the beneficiaries chosen by state law, "rather than to those identified in the plan documents." 532 U.S. at 147. The Court held that the statute thus ran counter to, among other things, ERISA's command that the fiduciary shall administer the plan in accordance with the documents and instruments governing the plan. *Id.* *Egelhoff* thus stands for the proposition that a state law that reassigns obligations contained within the documents and instruments governing an ERISA plan necessarily "relates to" the ERISA plan and is preempted.

Second, although the United States contends that this Court rejected "a materially identical argument" in *UNUM Life Insurance Co. of America* v. *Ward*, 526 U.S. 358 (1999), it misapprehends the holding of *UNUM* and its relationship to this case. In *UNUM*, an insurance company argued that a state law that fell within ERISA's savings clause for state insurance regulations, 29 U.S.C. §1144(b)(2), was nevertheless preempted because it conflicted with a written plan term. 526

U.S. at 375. The Court rejected that argument, reasoning that allowing insurers to "displace any state regulation simply by inserting a contrary term in plan documents" would "virtually read the saving clause out of ERISA." *Id.* at 376.

UNUM did not address a case like this one, where a state law conflicts with the terms of a *self-funded ERISA plan* and thus cannot be saved from preemption by the insurance-savings clause. *See infra* pp. 55-56. The question in this case is whether Vermont's reporting requirements "relate to" an ERISA plan in the first instance. In answering that question, there should be no doubt that a state law that alters the commitments a plan makes to its members in plan documents "relates" to that plan and is thus subject to preemption under 29 U.S.C. §1144(a).

Indeed, the Court's decision in *UNUM* supports Liberty Mutual's position. In *UNUM*, there was apparently no dispute that the state law at issue "related to" an employee benefit plan and thus fell within the scope of ERISA's preemption clause. 526 U.S. at 367. Absent the insurance-savings clause, the law at issue in *UNUM* would have been preempted. Here, Vermont's reporting requirements—like the law at issue in *UNUM*—relate to an employee benefit plan because those requirements conflict with the terms of the Plan. Unlike the law at issue in *UNUM*, however, the insurance-savings clause does not save Vermont's reporting requirements as applied to Liberty Mutual's plan, because the plan is self-funded. *See infra* pp. 55-56.

3. There is no merit to the United States' argument that there is "no evident conflict between the terms of respondent's plan and the Vermont reporting requirements." U.S. Br. 34. The United States ap-

pears to suggest that a conflict could exist only if Liberty Mutual had included in its plan documents a promise to its Members to "refuse to report claims information to state authorities in compliance with state law." *Id.* But the relevant question is whether the Vermont law's requirements are inconsistent with Liberty Mutual's obligations to its members under the Plan, not whether Liberty Mutual has made an express promise to its members not to comply with state law.[28] As already discussed, here the Vermont law is inconsistent with Liberty Mutual's obligations to its members because it has the effect of reassigning the ultimate obligation to keep members' health information confidential from Liberty Mutual and its TPA to the State.

III. PETITIONER'S REMAINING ARGUMENTS LACK MERIT

A. Other Federal Statutes Do Not Support Petitioner's Position

Petitioner and the United States point to other federal enactments that, they contend, support the conclusion that ERISA does not preempt Vermont's reporting requirements. Pet. Br. 45-50; U.S. Br. 19-22. Those enactments yield no reason to doubt that Congress intended to preempt state laws requiring ERISA plans to report on a core activity of the plan: providing benefits by paying claims.

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[28] Under the United States' view, for example, there would be no conflict—and thus no preemption—in a case where plan documents and state law prescribed different rules for determining beneficiary status unless the plan also included language expressly stating that it would refuse to determine beneficiary status in compliance with state law.

1. Petitioner contends that the National Health Planning and Resources Development Act of 1974 (NHPRDA) shows that "Congress … could not have intended ERISA to preempt state data-collection efforts" and instead "contemplated both a substantial state role in developing health care policy and reliance on comprehensive data about state health care systems." Pet. Br. 46-47. Petitioner's reliance on that repealed statute is misplaced. The NHPRDA was relevant to this Court's decision in *Travelers* that ERISA does not preempt state health care rate regulation because the NHPRDA envisioned a system of state regulation covering the same ground as the New York law at issue. The Court observed that the "the statute's provision for comprehensive aid to state health care rate regulation is simply incompatible with pre-emption of the same by ERISA." 514 U.S. at 667. Preempting the New York law "would have rendered the entire NHPRDA utterly nugatory, since it would have left States without the authority to do just what Congress was expressly trying to induce them to do by enacting the NHPRDA." *Id.*

The NHPRDA has no relevance to the kind of state regulation at issue here. That statute did not direct the States to collect claims information from ERISA plans or even express a general intent that States should be able to do so. Indeed, the first state statute imposing claims reporting requirements on self-insured plans was not enacted until 2003, decades after Congress enacted the NHPRDA. There is no conflict between a holding that ERISA preempts state reporting requirements and the scope of state regulation envisioned by the NHPRDA.

2. Petitioner and the United States also identify various provisions of the Patient Protection and Af-

fordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119 (2010), that supposedly "rely on or encourage state data-collection efforts similar to Vermont's." U.S. Br. 20; *see also* Pet. Br. 48-50. Congress's enactment of the ACA, however, says nothing about what Congress meant when it enacted ERISA's preemption provision 36 years earlier. "[T]he views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." *Marvin M. Brandt Revocable Trust* v. *United States*, 134 S. Ct. 1257, 1268 (2014).

In any event, the ACA provisions are fully consistent with preemption of Vermont's reporting requirements as applied to ERISA plans. The ACA provision authorizing the Secretary of Health and Human Services (HHS) to provide Medicare claims data for use in state claims databases, 42 U.S.C. §1395kk(e), illustrates merely that the federal government can decide what use it will make of the claims data in its own possession. That Congress decided, voluntarily, to give the federal government's own claims data to the States provides no reason to believe that Congress thought *each State* could *mandate* the same and other information from ERISA plans.

Nor would preemption adversely affect the Center for Medicare and Medicaid Innovation (CMMI). The ACA established CMMI for the purpose of "test[ing] innovative payment and service delivery models to reduce program expenditures." 42 U.S.C. §1315a(a)(1). The statute provides a non-exhaustive list of 24 models that CMMI "may" test, including "[a]llowing States to test and evaluate systems of all-payer payment reform for the medical care of residents of the State." *Id.* §1315a(b)(2)(B)(xi). The United States argues that preemption of APCD statutes "would impede CMMI's statutory mission" by depriving it of "access to com-

prehensive state-level databases" that are "important for evaluating models." U.S. Br. 20-21. But nothing in the ACA *requires* the existence of state APCDs that obtain information from ERISA plans and, at any rate, nothing prevents the federal government from requiring plans to report claims data directly to a federal agency, pursuant to a uniform federal standard. Separate state reporting requirements are not necessary for CMMI to discharge its statutory duties.[29]

Indeed, the ACA imposes new *federal* reporting requirements on ERISA plans, including ones mandating disclosure of "[c]laims payment policies and practices," "[d]ata on enrollment," and "[d]ata on the number of claims that are denied." 42 U.S.C. §18031(e)(3)(A); *see id.* §300gg-15a (making requirements applicable to "group health plans"); *see also* 29 U.S.C. §1191b(a)(1) (defining "group health plan" to include ERISA plan). The ACA then directs the Secretary of Labor to "update and harmonize" existing ERISA disclosure rules with the new standards the Secretary of HHS establishes to implement the ACA's new reporting requirements. 42 U.S.C. §18031(e)(3)(D). And the ACA amends ERISA to make clear that the ACA's new fed-

[29] Petitioner also asserts that HHS has awarded grants to States to encourage APCDs. Pet. Br. 49-50. But those grants have been provided to States with and without APCDs, indicating that they do not depend on APCDs. *See* CMS, Rate Review Grants, https://www.cms.gov/CCIIO/Resources/Rate-Review-Grants (last visited Oct. 13, 2015). And in any event, a federal agency's decision to award grants sheds no light on congressional intent as to ERISA's preemptive scope.

eral requirements "shall apply" to ERISA plans. 29 U.S.C. §1185d(a)(1).[30]

The fact that Congress enacted those changes but left ERISA's preemption clause untouched is telling. It illustrates Congress's continued recognition that reporting requirements would be imposed on ERISA plans only by the federal government and would need to be harmonized under a *federal* standard. Congress saw no reason to disturb the settled understanding that reporting by employee benefit plans falls exclusively within the federal domain.[31]

3. To the extent congressional action subsequent to ERISA is relevant, it points in favor of preemption. In 1974, Hawaii passed its Prepaid Health Care Act, which "required workers in the State to be covered by a comprehensive prepaid health care plan" and imposed "certain reporting requirements which differ[ed] from those of ERISA." *Standard Oil Co. of Cal.* v. *Agsalud*, 442 F. Supp. 695, 696 (N.D. Cal. 1977), *aff'd*, 633 F.2d 760 (9th Cir. 1980), *aff'd*, 454 U.S. 801 (1981). Hawaii's

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[30] The ACA makes other changes to ERISA as well, including specifically to ERISA disclosure and reporting requirements. *See* ACA §6606, 124 Stat. 781, *amending* 29 U.S.C. §1021(g).

[31] The ACA does not *expand* ERISA preemption, as the United States suggests Liberty Mutual might argue. U.S. Br. 21. Rather, the ACA *confirms* that ERISA makes reporting requirements exclusively federal. Particularly unpersuasive is the government's reliance on 29 U.S.C. §1191(a)(2), as that provision makes clear that there is "*[c]ontinued preemption* with respect to group health plans" (emphasis added). Moreover, the government's recognition that ACA's reporting requirements "focus on *plans* as such," U.S. Br. 22, confirms that reporting requirements implicate core ERISA plan functions. Although Vermont's law is broader than only ERISA plans, it is preempted as applied to ERISA plans.

implementing regulation required all "health care contractors"—which could include self-insurers—to report annually to the State information much like the information Vermont seeks for use in its claims database, including the "[n]umber of claims filed by covered employees," the "[n]umber of claims paid to covered employees," and the "[a]mount of claims paid to covered employees." JA188, JA196-197. The lower courts held that ERISA preempted the Hawaii law, including its reporting requirements, and this Court summarily affirmed. *Agsalud* v. *Standard Oil Co. of Cal.*, 454 U.S. 801 (1981).

Congress subsequently amended ERISA to exempt portions of the Hawaii statute from preemption. But "[t]he amendment did not exempt from preemption those portions of the law dealing with reporting, disclosure, and fiduciary requirements." *Fort Halifax*, 482 U.S. at 13 n.7 (citing 29 U.S.C. §1144(b)(5)). Congress's decision to leave Hawaii's reporting requirements preempted indicates its agreement that such requirements lie within the scope of ERISA's preemption provision. There is no reason to believe that Congress would think differently about Vermont's similar reporting requirements.

B. Vermont's Reporting Requirements Are Not Shielded From Preemption As a Generally Applicable State Health Care Regulation

1. Relying heavily on this Court's decisions in *Travelers* and *De Buono*, petitioner and the United States argue that Vermont's reporting regime is not preempted because it is merely "an exercise of traditional and longstanding state authority to regulate health care." Pet. Br. 29; *see* U.S. Br. 23-24. Further, petitioner argues, preemption here would "cast doubt

on common state laws that protect health and safety." Pet. Br. 44. That alarmist argument is without merit.

Vermont's reporting regime has an entirely different focus than the laws at issue in *Travelers* and *De Buono*. Vermont demands records and reports from those who pay for health care benefits. That is what employee welfare benefit plans, by their very nature, do: They pay for employee benefits. Although the Vermont regime is not limited to ERISA plans, it covers them because they engage in the very activity that makes them ERISA plans.

The state laws upheld in *Travelers* and *De Buono* operated completely differently. Unlike Vermont's Database Statute, they were not directed at the payment of benefits. Rather, those laws were directed at hospitals, not insurers and other health care payers, and this Court explained that laws regulating hospitals should be understood as general health care regulation, not regulation of welfare plans covered by ERISA. Indeed, the law at issue in *Travelers* did not even apply to ERISA plans; the law required hospitals to collect surcharges on hospital bills paid by commercial insurers but not on hospital bills paid by Blue Cross and Blue Shield Plans. 514 U.S. at 649. Although the law in *De Buono*, which imposed a gross receipts tax on the income of hospitals, did apply to some ERISA plans, the law did not apply to self-insured plans because the plans were engaging in their core ERISA activity of paying benefits. Rather, the law applied to the plans at issue because they had chosen to provide health benefits by operating their own hospitals and thus were subject to the state law. 520 U.S. at 809. That the hospitals were operated by ERISA plans was a happenstance; as the Court explained, "[m]ost hospitals are not owned or operated by ERISA funds." *Id.* at 816.

Here, by contrast, the application of Vermont's reporting regime to ERISA plans is not a happenstance. The scope of the Database Statute and the implementing Regulation are expressly defined to include administrators of self-insured employee benefit plans within the reach of the reporting regime. *See supra* pp. 5-7. Self-insured plans are included not because they have entered another line of business subject to state regulation (like hospitals) but because they are doing exactly what they were established to do.

That point explains why petitioner's other examples of state laws that would supposedly fall are flawed. Pet. Br. 44. Those laws would apply to ERISA plans not because they provide benefits under a plan, but because they choose to engage in other activities that are subject to state regulation. For example, the obligation that a plan-run hospital "report infections, mortality, or other public health data" does not arise because a self-insured plan is engaged in its core function of providing medical benefits, but because the plan chooses to operate a hospital subject to state laws directed at hospitals generally. *Cf. De Buono*, 520 U.S. at 809. Similarly, state requirements that day care centers report on attendance, safety measures, or teacher qualifications can be applied to plan-run day care centers because such reporting obligations are not directed at the core plan activity of providing benefits.

Contrary to petitioner's suggestion (Pet. Br. 40), the court of appeals below did not hold—and Liberty Mutual does not contend—"that requiring a plan to provide information for any purpose, in any context, intrudes on a core ERISA function." Rather, the court of appeals properly noted that ERISA's preemption provision allows for reporting laws that "create no impediment to an employer's adoption of a uniform bene-

fit administration scheme" and have "too tenuous, remote or peripheral an effect on employee benefit plans." Pet. App. 24. The court made clear, however, that Vermont's reporting requirements are different from such laws because they "implicate an ERISA core administrative concern" by requiring ERISA plans to report "information about the essential functioning of employee health plans." *Id.* 29 n.13. There is nothing "tenuous, remote or peripheral" about a state administrative obligation that arises as a result of ERISA plans providing benefits to their participants.

2. Certain amici suggest that state APCD laws like Vermont's could be understood as an aspect of the State's regulation of insurance and potentially be saved from preemption by ERISA's insurance-savings clause, 29 U.S.C. §1144(b)(2)(A). *See* NGA Br. 9 n.12; AMA Br. 27 n.11. This Court ordinarily will not consider arguments raised only by an amicus. *Robertson* v. *Seattle Audubon Soc'y*, 503 U.S. 429, 441 (1992). In any event, the argument is without merit.

Even if the Database Statute fell within ERISA's insurance-savings clause, it nonetheless could not be applied to a self-insured plan like the Liberty Mutual Plan because of ERISA's "deemer" clause, 29 U.S.C. §1144(b)(2)(B). That clause prevents States from extending even their "generally applicable" insurance regulations to self-insured employee benefit plans. *See FMC*, 498 U.S. at 61; *Metropolitan Life*, 471 U.S. at 748. The deemer clause also prevents States from indirectly regulating self-insured plans through their TPAs. *See America's Health Ins. Plans* v. *Hudgens*, 742 F.3d 1319, 1333-13334 n.18 (11th Cir. 2014); *Prudential Ins. Co. of Am.* v. *National Park Med. Ctr., Inc.*, 413 F.3d 897, 912-913 (8th Cir. 2005). The deemer clause thus reinforces

that Vermont's reporting regime, as applied to the Liberty Mutual Plan, is preempted by ERISA.

C. Liberty Mutual's Use Of A Third-Party Administrator Does Not Exempt Vermont's Reporting Mandate From ERISA

Petitioner and the United States also argue that Liberty Mutual cannot show that ERISA preempts Vermont's reporting requirements because Liberty Mutual uses a third party to administer its plan. Pet. Br. 53-54; U.S. Br. 28-29. As the Second Circuit and others have explained, however, "'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.'" Pet. App. 23 n.10 (quoting *Pharmaceutical Care Mgmt. Ass'n* v. *District of Columbia*, 613 F.3d 179, 182 (D.C. Cir. 2010)); *see also America's Health Ins. Plans*, 742 F.3d at 1331-1332; *NGS Am., Inc.* v. *Barnes*, 998 F.2d 296, 300 (5th Cir. 1993). ERISA preempts state laws that disrupt uniform administration by "plan administrators," *Egelhoff*, 532 U.S. at 150, whether those administrators are employed directly by the plan or by a third party that charges the plan for their services.

Liberty Mutual pays its TPA for the costs of administering its plan. Although the TPA may encounter the burden of reporting Liberty Mutual's data to Vermont (and other States) in the first instance, Liberty Mutual will ultimately compensate its TPA for those additional costs of administration. In an efficient market, after all, third-party administrators fully pass on their costs to self-insured plans. *See East Tex. Baptist Univ.* v. *Burwell*, 793 F.3d 449, 460 (5th Cir. 2015).

There is no statutory, doctrinal, or policy basis for exempting Vermont's reporting requirement from

ERISA preemption simply because Liberty Mutual's TPA actually undertakes the reporting obligation. To hold otherwise would only discourage ERISA plans from using TPAs at a time when they have become increasingly important as plan administration has grown more complex. *See* Advisory Council on Employee Welfare and Pension Benefit Plans, Outsourcing Employee Benefit Plan Services: Report to the U.S. Secretary of Labor 4-6 (Nov. 2014), *available at* http://www.dol.gov/ebsa/pdf/2014ACreport3.pdf. And Liberty Mutual's choice whether to have its benefits administered in-house or by a TPA is itself a matter of plan administration that ERISA leaves to the plan's judgment; under ERISA's preemption clause, that choice should not be affected by the operation of state law. *See Pharmaceutical Care Mgmt. Ass'n*, 613 F.3d at 188.

Moreover, petitioner's argument elides that both self-insured plans and their TPAs fall within the Vermont regulation's definition of a "Health Insurer" that must report data. *See* Regulation H-2008-01 §3(X).[32] The only reason Liberty Mutual is itself not a mandatory reporter is that it currently has fewer than 200 members in Vermont, but that may change. Even now, the burden of complying with Vermont's regulation falls on Liberty Mutual; the TPA has Liberty Mutual's data and is required to report that data solely because of the services it provides Liberty Mutual, and the Plan will ultimately bear the cost of reporting.[33]

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[32] Petitioner now suggests that self-insured plans might not fall within the definition, Pet. Br. 53 n.33, but it did not dispute below that they did, *see* Pet. App. 54.

[33] Certain amici suggest that APCD laws implicate self-insured plans' claims data only because those laws apply to third-party administrators (along with traditional insurers), but not self-

D. This Court's Mode Of Preemption Analysis Does Not Change The Relevant Inquiry

Finally, petitioner and the United States discuss whether ERISA preemption is best analyzed as a form of "field preemption." *See* Pet. Br. 30 n.16; U.S. Br. 30-32. Several Justices have suggested that ERISA preemption cases are best analyzed under the field-preemption rubric. *E.g.*, *Dillingham*, 519 U.S. at 336 (Scalia, J., concurring); *see also Egelhoff*, 532 U.S. at 153 (Breyer, J., dissenting). It is unnecessary to resolve that debate in this case. The result in this case would not be different if the express-preemption or the field-preemption approach were used (and petitioner does not argue otherwise). The field that is preempted by ERISA, employee benefit plans, encompasses reporting and disclosure about the core activities of those plans, including paying benefits under a plan. ERISA established uniform reporting requirements, not minimum ones. Because Vermont's mandate purports to supplement those requirements, it is preempted.[34]

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insured plans themselves. *See* N.Y. Br. 31. Whatever the merits of that point regarding other state laws, it is clearly inapplicable to Vermont, which has extended its regime to self-insured plans themselves. *See supra* pp. 5-7. In any event, that claims data may be in the hands of a TPA is irrelevant; the information belongs to the plan, and the plan will ultimately bear the burden of ensuring that it is reported to the State.

[34] What would be clearly wrong would be to reduce ERISA preemption to a question of conflict preemption. *Cf.* U.S. Br. 31-35. ERISA contains a broad express preemption provision, and this Court's cases clearly recognize that the scope of preemption under that provision is far broader than the application of this Court's conflict-preemption jurisprudence. *See Metropolitan Life*, 471 U.S. at 737.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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APPENDIX

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

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, anything in the constitution or laws of any state to the contrary notwithstanding.

UNITED STATES CODE

TITLE 29. LABOR
CHAPTER 18. EMPLOYEE RETIREMENT INCOME SECURITY PROGRAM

29 U.S.C. §1002. Definitions

For purposes of this subchapter:

(1) The terms "employee welfare benefit plan" and "welfare plan" mean any plan, fund, or program which was heretofore or is hereafter established or maintained by an employer or by an employee organization, or by both, to the extent that such plan, fund, or program was established or is maintained for the purpose of providing for its participants or their beneficiaries, through the purchase of insurance or otherwise, (A) medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, death or unemployment, or vacation benefits, apprenticeship or other training programs, or day care centers, scholarship funds, or prepaid legal services, or (B) any benefit described in section 186(c) of this title (other than pensions on retirement or death, and insurance to provide such pensions).

* * *

(3) The term "employee benefit plan" or "plan" means an employee welfare benefit plan or an employee pension benefit plan or a plan which is both an employee welfare benefit plan and an employee pension benefit plan.

* * *

29 U.S.C. §1023. Annual reports

(a) Publication and filing

(1)(A) An annual report shall be published with respect to every employee benefit plan to which this part applies. Such report shall be filed with the Secretary in accordance with section 1024(a) of this title, and shall be made available and furnished to participants in accordance with section 1024(b) of this title.

* * *

(e) Statement from insurance company, insurance service, or other similar organizations which sell or guarantee plan benefits

If some or all of the benefits under the plan are purchased from and guaranteed by an insurance company, insurance service, or other similar organization, a report under this section shall include a statement from such insurance company, service, or other similar organization covering the plan year and enumerating—

(1) the premium rate or subscription charge and the total premium or subscription charges paid to each such carrier, insurance service, or other similar organization and the approximate number of persons covered by each class of such benefits; and

(2) the total amount of premiums received, the approximate number of persons covered by each class of benefits, and the total claims paid by such company, service, or other organization; dividends or retroactive rate adjustments, commissions, and administrative service or other fees or other specific acquisition costs paid by such company, service, or other organization; any amounts held to provide benefits after retirement; the remainder of such

premiums; and the names and addresses of the brokers, agents, or other persons to whom commissions or fees were paid, the amount paid to each, and for what purpose. If any such company, service, or other organization does not maintain separate experience records covering the specific groups it serves, the report shall include in lieu of the information required by the foregoing provisions of this paragraph (A) a statement as to the basis of its premium rate or subscription charge, the total amount of premiums or subscription charges received from the plan, and a copy of the financial report of the company, service, or other organization and (B) if such company, service, or organization incurs specific costs in connection with the acquisition or retention of any particular plan or plans, a detailed statement of such costs.

* * *

29 U.S.C. §1024. Filing with Secretary and furnishing information to participants and certain employers

(a) Filing of annual report with Secretary

(1) The administrator of any employee benefit plan subject to this part shall file with the Secretary the annual report for a plan year within 210 days after the close of such year (or within such time as may be required by regulations promulgated by the Secretary in order to reduce duplicative filing). The Secretary shall make copies of such annual reports available for inspection in the public document room of the Department of Labor.

(2)(A) With respect to annual reports required to be filed with the Secretary under this part, he may by

regulation prescribe simplified annual reports for any pension plan which covers less than 100 participants.

(B) Nothing contained in this paragraph shall preclude the Secretary from requiring any information or data from any such plan to which this part applies where he finds such data or information is necessary to carry out the purposes of this subchapter nor shall the Secretary be precluded from revoking provisions for simplified reports for any such plan if he finds it necessary to do so in order to carry out the objectives of this subchapter.

(3) The Secretary may by regulation exempt any welfare benefit plan from all or part of the reporting and disclosure requirements of this subchapter, or may provide for simplified reporting and disclosure if he finds that such requirements are inappropriate as applied to welfare benefit plans.

* * *

29 U.S.C. §1104. Fiduciary duties

(a) Prudent man standard of care

(1) Subject to sections 1103(c) and (d), 1342, and 1344 of this title, a fiduciary shall discharge his duties with respect to a plan solely in the interest of the participants and beneficiaries and—

(A) for the exclusive purpose of:

(i) providing benefits to participants and their beneficiaries; and

(ii) defraying reasonable expenses of administering the plan;

(B) with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims;

(C) by diversifying the investments of the plan so as to minimize the risk of large losses, unless under the circumstances it is clearly prudent not to do so; and

(D) in accordance with the documents and instruments governing the plan insofar as such documents and instruments are consistent with the provisions of this subchapter and subchapter III of this chapter.

(2) In the case of an eligible individual account plan (as defined in section 1107(d)(3) of this title), the diversification requirement of paragraph (1)(C) and the prudence requirement (only to the extent that it requires diversification) of paragraph (1)(B) is not violated by acquisition or holding of qualifying employer real property or qualifying employer securities (as defined in section 1107(d)(4) and (5) of this title).

* * *

29 U.S.C. §1143. Research, studies, and reports

(a) Authorization to undertake research and surveys

(1) The Secretary 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, including retirement, deferred compensation, and welfare plans, and types of plans not subject to this chapter.

(2) The Secretary is authorized and directed to undertake research studies relating to pension plans, including but not limited to (A) the effects of this subchapter upon the provisions and costs of pension plans, (B) the role of private pensions in meeting the economic security needs of the Nation, and (C) the operation of private pension plans including types and levels of benefits, degree of reciprocity or portability, and financial and actuarial characteristics and practices, and methods of encouraging the growth of the private pension system.

(3) The Secretary may, as he deems appropriate or necessary, undertake other studies relating to employee benefit plans, the matters regulated by this subchapter, and the enforcement procedures provided for under this subchapter.

(4) The research, surveys, studies, and publications referred to in this subsection may be conducted directly, or indirectly through grant or contract arrangements.

* * *

29 U.S.C. §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, insur-

ance 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. 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 Co-

lumbia 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) Automatic contribution arrangements

(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.

29 U.S.C. §1204. Coordination between the Department of the Treasury and the Department of Labor

(a) Whenever in this chapter or in any provision of law amended by this chapter the Secretary of the Treasury and the Secretary of Labor are required to carry out provisions relating to the same subject matter (as determined by them) they shall consult with each other and shall develop rules, regulations, practices, and forms which, to the extent appropriate for the efficient administration of such provisions, are designed to reduce duplication of effort, duplication of reporting, conflicting or overlapping requirements, and the burden of compliance with such provisions by plan administrators, employers, and participants and beneficiaries.

* * *

VERMONT STATUTES ANNOTATED

TITLE EIGHTEEN. HEALTH
PART 9. UNIFIED HEALTH CARE SYSTEM
CHAPTER 221. HEALTH CARE ADMINISTRATION
SUBCHAPTER 1. QUALITY, RESOURCE ALLOCATION, AND COST CONTAINMENT

18 V.S.A. §9402. Definitions

* * *

(8) "Health insurer" means any health insurance company, nonprofit hospital and medical service corporation, managed care organizations, and, 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.

* * *

18 V.S.A. §9410. Health care database

(a)(1) The Board shall establish and maintain a unified health care database to enable the Board to carry out its 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) [Repealed.]

(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, 2018 and every three years thereafter, the Commissioner of Health shall submit a recommendation to the General Assembly for conducting a survey of the health insurance status of Vermont residents. The provisions of 2 V.S.A.

§20(d)(expiration of required reports) shall not apply to the report to be made under this subsection.

(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.

VERMONT DEPARTMENT OF BANKING, INSURANCE, SECURITIES AND HEALTH CARE ADMINISTRATION

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 non-residents 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 en-

rollees 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 uti-

lized 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, Tri-

care, 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 trans-

mittal 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 nonbinding 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 ap-

plication 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.