**MAINE HEALTH DATA ORGANIZATION:**

**Law, History, Purpose, Powers and Duties**

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1. A Bit About Reading the Law[[1]](#footnote-1)

 **The Constitution:** In the United States there are two major systems of law- federal and state. These systems contain many similarities in form and procedure. They are also very interactive since the federal constitution provides baseline protections for citizens that the states cannot infringe upon. The federal law is based on the United States Constitution, the foundation of the federal government. Federal law includes statutes enacted by congress, regulations promulgated by the executive branch, and case law made by the federal judiciary. Under the US Constitution federal law is limited to areas set out in the constitution. These include borrowing money, regulating commerce, coining money, establishing post offices and roads, granting copyrights and patents, etc. In actuality, the federal government regularly uses the interstate commerce clause to regulate in just about any area.

 Similarly each state has its own constitution that in many ways follow the federal constitution. The state systems also each have their own legislatures, statutes, agencies and judiciary. The laws most people deal with day-to-day such as contracts, property, criminal and family law are mostly state law. Each state has sovereignty and can enact any laws it wants, except a state cannot unduly limit an individual’s rights if protected in the United States Constitution.

 **Statutes:** Both federal and state governments have legislative bodies that create laws. On the federal level this is the United States Congress. Once the President signs a bill into law (or Congress enacts it over a veto) the law is codified in the United States Code (“USC”) along with all the other general and permanent laws of the United States. The United States Code looks like a large encyclopedia. The code is divided into titles by subject matter. Titles are then divided into chapters and sections. For example the Health Insurance Portability and Accountability Act of 1996 ended up codified at Title 42 of the United States Code at sections1320(d-1)-(d-8). This citation is usually abbreviated to 42 U.S.C. §§1320(d-1) *et seq.*

 One of the many confusing aspects of codification is that the sections of any new Act as enacted will be entirely re-numbered to fit into the code in the appropriate title, chapter and section. So, knowing an item is in a certain section of the act (and laws are often cited this way) will not tell you where it is in the code. In addition any act may make changes to many different titles in the code, and so the sections of an act may not even end up in the same title of the code.

 In the State of Maine’s system, each Act is assigned a legislative document (“LD”) number so it can be identified as it works its way through the Maine legislature. For example the statute MHDO worked in the 126th Legislature (2013-2014) was LD 1740 “An Act to Amend the Laws Relating to Health Care Data.” When that Act was approved by the Governor and became law it became Public Law (“PL”) 2013, Chapter 528. Unlike federal Acts, Maine LDs give both the section numbers for the LD, and the title and sections of the Maine Revised Statutes (“MRS”) where the changes will be codified.[[2]](#footnote-2)

 Once the PL is codified (published) on the legislature’s webpage for the Maine Revised Statutes, it will be in the correct Title and Section with a citation at the end of the amended or new paragraph, “2013, c.528” so anyone can find the chapter of public law that contains the change. The “enabling legislation” that created the MHDO is PL 1995 c.653. The MHDO enabling legislation is codified at 22 MRS Chapter 1683 (§§8701-8713).

 **Rules and Regulations**: Most statutes at the federal level result in lots of federal regulations promulgated by executive branch agencies. For example, the HIPAA regulations were developed by the federal Department of Health and Human Services. These federal regulations are codified in the Code of Federal Regulations. This is another (very) large set of books. These are arranged according to their own titles and divided up into parts and sections. For example the HIPAA regulation which states that “a covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law” is at Title 45 of the Code of Federal Regulations (“CFR”) at Section 164.512(a)(1). The abbreviation of this is 45 CFR §164.512(a)(1).

 In Maine agencies enact their regulations according to standard rulemaking requirements in Maine’s Administrative Procedures Act (“MAPA”), Title 5, Chapter 375. The sections on rulemaking are 5 MRS §§8051-8074. Rulemaking statutes are aimed at keeping the rulemaking process open to public participation and comment. Regular rules are called “routine-technical.” Maine also has a distinct type of rules called “major substantive.” Major substantive rules are those that require the exercise of significant agency discretion or interpretation or because of their subject matter or anticipated impact are reasonably expected to result in significant financial impact on the regulated community (including county and municipal governments) or significant reductions of government benefits or services. 5 MRS §8071(B). For such rules, the legislature has an opportunity to review and consider the rule, and make any changes it wants or even refuse to approve adoption of the rule. 5 MRS §8072.

 Adopted rules are published by Maine’s Secretary of State in the Code of Maine Rules (“CMR”).[[3]](#footnote-3) MHDO’s rules are in Section 90-590 of the CMR. MHDO has 10 sets or “chapters” of rules currently. Each chapter of rules has its own number. For example MHDO’s rules on Release of Data to the Public are at 90-590 CMR, Chapter 120. MHDO has both routine-technical and major-substantive rules.

 **The Judicial System.** Laws are interpreted by judges. This happens, for example, when someone files a case in court because they disagree with how an agency has applied the law in its regulations, or they think a law violates the US Constitution. The result is that judges can have a great effect on the law. For example judges decide questions about how a law is to be interpreted, and they can strike down statutes as unconstitutional. Once a judge has done so, anyone in that court’s jurisdiction has to abide by that interpretation or ruling, unless it is changed by a higher court. The trial (lowest) level of the federal court is the United States District Court. Maine has one in Portland, and one in Bangor. The appeals level of the federal court system is divided up into 13 circuits. Maine is in the First Circuit which sits at Boston. Also in the First Circuit are Massachusetts, New Hampshire, Rhode Island and Puerto Rico. Appeals from the Circuit Courts of Appeal go to the Supreme Court of the United States.

 For example, in 2006 a number of states including Maine enacted laws to prevent or control pharmaceutical manufacturers from “data mining” the prescriptions of individual doctors by restricting the sale, disclosure and use of pharmacy records that reveal the prescribing practices of individual doctors. Maine’s law was PL2007, c.460 “An Act to Amend the Prescription Privacy Law.” This Act made a number of changes and additions to Title 22 (Health and Welfare) of the MRS, including changes to MHDO’s Chapter 1683. It enacted 22 MRS §8713, which stated MHDO “shall establish procedures to accept filing of confidentiality protection from health care practitioners who file with the organization under section 1711-E, subsection 4 and licensing boards that submit lists of names of practitioners who file for confidentiality protection….” The constitutionality of the entire act, including those provisions changing MHDO’s statute was challenged in federal court by a data mining company named IMS Health Corp.

 IMS brought cases in several states that had enacted similar laws. The central question was whether allowing prescribers to prevent disclosure and sale of their prescribing history by pharmacies to prescription data miners, who then sold the information to pharmaceutical companies, was an impermissible restriction of commercial speech in violation of the First Amendment to the US Constitution. In Maine, the US District Court enjoined (prevented) the Maine Attorney General’s office from enforcing the new law. The First Circuit found the law *was* constitutional concluding that it regulated conduct not speech. So the First Circuit reversed the US District Court. *IMS Health Inc., et al, v. Mills*, 616 F.3d 7 [this part of the citation tells where the case is printed](1st Cir. 2010)[this tells which circuit court decided it and when]. The case was then appealed to the Supreme Court of the United States.

 In a related case from Vermont the US Supreme Court held that such laws were an impermissible restriction on free speech, because they were not justified by the state’s asserted interests in protecting doctors’ confidentiality, and protecting doctors from harassing sales behaviors. Also, the statute did not permissibly advance the state’s policy goals of lowering the costs of medical services and promoting public health. *Sorrell, v. IMS Health Inc.*, 131 S.Ct. 2653 (2011). After *Sorrell* was decided, the US Supreme Court vacated the decision of the First Circuit in Maine’s case, and sent the case back for “further consideration, in light of *Sorrell*….” *IMS Health, Inc., et al, v. Schneider*, 131 S.Ct. 3091 (2011).

 As a result, PL 2011, c. 494 “An Act to Conform Maine’s Prescription Drug Privacy Laws with the United States Constitution,” was enacted by the Maine legislature. As you may guess, this act repealed most of the prior act, including those sections having to do with the MHDO. So now if you look up 22 MRS §8713 on the Maine legislature’s website you will see: “**§8713. Confidentiality protection for certain health care practitioners, *(REPEALED),*** SECTION HISTORY: 2007, c. 460, §4 (NEW). 2011, c. 494, §9 (RP).”

 The state court system works similarly. In Maine, the District Court is the lowest level, the Superior Court is next, and the Maine Supreme Court (also called the Law Court), is the highest court in this state. MHDO could take certain cases to state court. For example, if one of the hospitals who was supposed to pay an assessment did not, you could file in superior court for an injunction (court order) compelling them to pay. If they still did not pay, MHDO could ask for contempt sanctions to be imposed.

II. The Purpose of Maine Health Data Organization

The Maine Health Data Organization (“MHDO”) was established in 1995 by the Maine Legislature to succeed the former Maine Health Care Finance Commission (“MHCFC”). Whereas MHCFC was established to monitor and regulate hospital charges, the MHDO was created in order to collect and analyze clinical, financial and restructuring data from health care facilities and providers of health care. Most, but not all of the laws requiring MHDO to do things, are in 22 MRS Chapter 1683 (§§8701-8713). The statutes regarding MHDO’s purpose currently read as follows:

**§8701. Declaration of purpose**

It is the intent of the Legislature that uniform systems of reporting health care information be established; that all providers and payors who are required to file reports do so in a manner consistent with these systems; and that, using the least restrictive means practicable for the protection of privileged health care information, public access to those reports be ensured.

**§8703. Maine Health Data Organization established**

The Maine Health Data Organization is established as an independent executive agency. [1995, c. 653, Pt. A, §2 (NEW); 1995, c. 653, Pt. A, §7 (AFF).]

**1.** **Objective.**  The purposes of the organization are to create and maintain a useful, objective, reliable and comprehensive health information database that is used to improve the health of Maine citizens and to issue reports, as provided in section 8712. This database must be publicly accessible while protecting patient confidentiality and respecting providers of care. The organization shall collect, process, analyze and report clinical, financial, quality and restructuring data as defined in this chapter.

**2.** **Board of directors.**  The organization operates under the supervision of a board of directors, which consists of 20 voting members and one nonvoting member. …

1. Requirements of the MHDO Board of Directors

 MHDO’s enabling statute makes a number of requirements of the board, but also gives it some broad authority and power to go beyond what the legislature requires. I’ll review the requirements first.Basic duties of the board are laid out in §8704.

**§8704. Powers and duties of the board. …**

* **Uniform reporting systems.**  The board shall establish uniform reporting systems.

A. The board shall develop and implement policies and procedures for the collection, processing, storage and analysis of clinical, financial, quality and restructuring data in accordance with this subsection for the following purposes:

(1) To use, build and improve upon and coordinate existing data sources and measurement efforts through the integration of data systems and standardization of concepts;

(2) To coordinate the development of a linked public and private sector information system;

(3) To emphasize data that is useful, relevant and not duplicative of existing data;

(4) To minimize the burden on those providing data; and

(5) To preserve the reliability, accuracy and integrity of collected data while ensuring that the data is available in the public domain.

B. Information and data required to be filed pursuant to this chapter must be filed annually or more frequently as specified by the organization. The organization shall establish a schedule for compliance with the required uniform reporting systems….

E. The board shall exempt from reporting by a provider data regarding a person who informs the provider of the person's objection, or the objection of a parent of a minor, to inclusion in data collection based on a sincerely held religious belief.…

* **Rulemaking.**  The board shall adopt rules necessary for the proper administration and enforcement of the requirements of this chapter. All rules must be adopted in accordance with Title 5, chapter 375 and unless otherwise provided are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A. …
* **Staff.**  The board shall appoint staff as needed to carry out the duties and responsibilities of the board under this chapter.…]

As stated above MHDO replaced the MHCFC. They also took over the data that had been collected by MHCFC. In the first few years of MHDO’s existence they were specifically required to collect certain data sets. At §8708 “Clinical Data” the responsibility of the MHDO to collect data includes adopting rules that mandate health care facilities to report hospital discharge data sets. The rules on this set of data are 90-590 CMR Chapter 241, “Uniform Reporting System for Hospital Inpatient Data Sets and Hospital Outpatient Data Sets.”

Section 8709 requires health care facilities to file financial information. The rules regarding this are 90-590 CMR Chapter 300 “Uniform Reporting System for Hospital Financial data.”

Section 8710, restructuring data, requires the MHDO board to adopt rules regarding reporting of major structural changes relevant to the restructuring and delivery and financing of health care in Maine and to the potential effects of that restructuring on consumers. These rules are at CMR 90-590 CMR Chapter 630 “Uniform System for Reporting Baseline Information and Restructuring Occurrences for Maine Hospitals and Parent Entities.”

The claims data reporting rules are at 90-590 CMR Chapter 243, “Uniform Reporting System for Health Care Claims Data Sets.” MHDO is required to collect claims data in order to make the reports required by §8712 (below), including the reports on “payments for services rendered by health care facilities and practitioners to residents of the state…” 22 MRS §§8703(1); 8712(2).

1. Quality Data and Price Transparency

In 2003 the Legislature expanded the data gathering and reporting responsibilities of the MHDO when it approved Governor Baldacci’s Dirigo Health legislation.[[4]](#footnote-4) Part C of that legislation added entirely new sections to MHDO’s enabling statute. These included 22 MRS §8708-A on Quality Data collection (in concert with the Maine Quality Forum). Also, 22 MRS §8712 was added. Now the MHDO is now required to produce “clearly labeled and easy-to-understand reports” on health care quality and payments that are publicly accessible.

These reports must allow comparison regarding health care services, their outcomes, the effectiveness of those services, and the quality of those services by facility and practitioner. Additionally, the MHDO is required to produce annual reports which compare prices for the 15 most common inpatient and outpatient hospital services, and services and procedures delivered by Maine physicians with similar health care services rendered in other states.

As a result of the Dirigo Health legislation, the MHDO Board was directed to adopt rules regarding the collection of quality data. [[5]](#footnote-5) The MHDO Board was required to work with the Maine Quality Forum and Maine Quality Forum Advisory Council in the development of these rules. [[6]](#footnote-6) MHDO’s rules on quality data are codified at 90-590 CMR Chapter 270, Uniform Reporting System for Quality Data Sets. These rules also fulfill another statutory requirement of MHDO. Title 22 MRS §8761 requires hospitals to report data on Methicillin-resistant Staphylococcus aureus (MRSA) and Clostridium difficile (C. diff). That law further requires MHDO to make rules regarding public reporting of data regarding MRSA and C. diff, which are in the Quality Data (Chapter 270) rules. These are major-substantive rules.

The enactment of the Dirigo Health legislation marks the point where the mission of MHDO expands beyond public access to data for consumers of health care data itself (“Superusers”). After 2003, MHDO is also responsible for presentation of the data, and specifically quality and payment data, in formats accessible to and understandable by, health care consumers.

Section 8712 has been added to and rearranged several times including by PL 2009, c. 350 “An Act to Protect Consumers and Small Business Owners from Rising Health Care Costs.” This Act added the requirement that MHDO “promote public transparency of the quality and cost of health care in the State…” An understanding of the various reports referred to is important because of MHDO’s purpose is to create and maintain a useful, objective, reliable and comprehensive health information database that is used to improve the health of Maine citizens and to issue reports, as provided in section 8712. 22 MRS §8703(1). Section **8712 Reports** currently reads:

“The organization shall produce clearly labeled and easy-to-understand reports as follows. Unless otherwise specified, the organization shall distribute the reports on a publicly accessible site on the Internet or via mail or e-mail, through the creation of a list of interested parties. The organization shall make reports available to members of the public upon request.

**1.** **Quality.**  The organization shall promote public transparency of the quality and cost of health care in the State in conjunction with the Maine Quality Forum established in Title 24-A, section 6951 and shall collect, synthesize and publish information and reports on an annual basis that are easily understandable by the average consumer and in a format that allows the user to compare the information listed in this section to the extent practicable. The organization's publicly accessible websites and reports must, to the extent practicable, coordinate, link and compare information regarding health care services, their outcomes, the effectiveness of those services, the quality of those services by health care facility and by individual practitioner and the location of those services. The organization's health care costs website must provide a link in a publicly accessible format to provider-specific information regarding quality of services required to be reported to the Maine Quality Forum. …

**2.** **Payments.**  The organization shall create a publicly accessible interactive website that presents reports related to payments for services rendered by health care facilities and practitioners to residents of the State. The services presented must include, but not be limited to, imaging, preventative health, radiology and surgical services and other services that are predominantly elective and may be provided to a large number of patients who do not have health insurance or are underinsured. The website must also be constructed to display prices paid by individual commercial health insurance companies, 3rd-party administrators and, unless prohibited by federal law, governmental payors. Beginning October 1, 2012, price information posted on the website must be posted semiannually, must display the date of posting and, when posted, must be current to within 12 months of the date of submission of the information. …

**3.** **Comparison report.**  At a minimum, the organization shall develop and produce an annual report that compares the 15 most common diagnosis-related groups and the 15 most common outpatient procedures for all hospitals in the State and the 15 most common procedures for nonhospital health care facilities in the State to similar data for medical care rendered in other states, when such data are available.

**4.** **Physician services.**  The organization shall provide an annual report of the 10 services and procedures most often provided by osteopathic and allopathic physicians in the private office setting in this State. The organization shall distribute this report to all physician practices in the State…. [2003, c. 469, Pt. C, §29 (NEW).]”

In addition, Section C of the Dirigo Health legislation enacted new 22 MRS §1718 requiring hospitals and ambulatory surgery centers to provide to requesting individuals, the average charge for any inpatient service or outpatient procedure provided by the hospital or surgical center. In addition, new 24 MRS §2987 (which has since been updated and moved to 22 MRS §1718-A) makes similar requirements of health care practitioners on prices the practitioner charges clients directly when there is no insurance coverage, or coverage is denied.

1. Other Requirements and Powers.

MHDO is required by 22 MRS §8705-A to make rules specifically regarding enforcement for data filing requirements, assessment payments and protection of identification of patients and health care practitioners. These rules are at 90-590 CMR Chapter 100, Enforcement Procedures. The MHDO was granted the authority to establish a forfeiture schedule to sanction those providers or payors who failed to adhere to their respective data reporting and assessment obligations, or who “willfully failed to safeguard the identity of patients, providers, health care facilities or 3rd party payors.”[[7]](#footnote-7) In addition to imposing civil forfeitures upon entities in violation of MHDO rules, the organization also has authority to initiate proceedings in Superior Court to enforce its rules.

MHDO must pay for its operations with data user fees and annual assessments on payers. 22 MRS §8706. The Determination of Assessments rule is at 90-590 CMR, Chapter 10. The Prices for Data Sets, Fees for Programming and Reports Generation, Duplication Rates rules are at 90-590 CMR, Chapter 50.

MHDO’s enabling statute at §8707 requires MHDO to adopt rules to provide for public access to data so long as it does not identity an individual; establish criteria for what is confidential information; and allow exceptions to confidentiality only for public health studies. These rules are at 90-590 CMR Chapter 120, Release of Data to the Public. This section and these rules are the ones most affected by LD 1740 (now PL 2013 c. 528). In 2001 the Legislature designated the data release rule as major substantive rules, subject to the review and approval of the Legislature.[[8]](#footnote-8)

In addition, 22 MRS §1711-C, the statute regarding confidentiality of health care information which applies to health care practitioners in Maine, requires that MHDO “adopt rules to define health care information that directly identifies an individual…” 22 MRS §1711-C(E). These rules are at 90-590 CMR Chapter 125, Health Care Information that Directly Identifies an Individual.

 Beside numerous requirements the MHDO has to fulfill it has the power to do even more. These powers include both executive type powers, to keep the organization functioning, and more substantive power and authority related to the collection of health care data.

 The enabling statute and the Maine Administrative Procedures Act speak to the general authority of the board to conduct its business. For example, MHDO Board is classified as a general government board in 5 MRS §12004-(G)(14-B). This means MHDO has the power to hold hearings, adopt rules, establish policies and procedures, enter into contracts, establish just charges, conduct investigations, acquire property, and enforce state laws. There is more about these general powers in the MHDO statute. See, 22 MRS §8704, and especially sub-section (11): “Other powers. The board may exercise all powers reasonably necessary to carry out the powers expressly granted and responsibilities expressly imposed by this chapter.”

Finally, the statute includes a few broad substantive, authorizations for MHDO to collect more data. Section 8708 gives MHDO authority to require providers and payors to provide additional “clinical data.” It reads as follows: “**Section 8708(6-A)** **Additional data,**  Subject to the limitations of section 8704, subsection 1, the board may adopt rules requiring the filing of additional clinical data from other providers and payors as long as the submission of data to the organization is consistent with federal law. Data filed by payors must be provided in a format that does not directly identify the patient.” The MHDO statute states "Clinical data" includes but is not limited to the data required to be submitted by providers and payors pursuant to sections 8708 and 8711. 22 MRS §8702(2). **Section** **8708(7)** states“**Authority to obtain information.**  Nothing in this section may be construed to limit the board's authority to obtain information that it considers necessary to carry out its duties.” [This is the sub-section changed by PL 2013, c.528 to require that before collecting any type of clinical data that it did not collect as of March 1, 2014, the MHDO shall adopt major-substantive rules regarding the definition, collection, use and release of clinical data.]

Finally MHDO has **§8711,** which states **“Other health care information… Development of health care information systems.**  In addition to its authority to obtain information to carry out the specific provisions of this chapter, the organization may require providers and payors to furnish information with respect to the nature and quantity of services or coverage provided to the extent necessary to develop proposals for the modification, refinement or expansion of the systems of information disclosure established under this chapter. The organization's authority under this subsection includes the design and implementation of pilot information reporting systems affecting selected categories or representative samples of providers and payors. [2007, c. 136, §7 (AMD).]”

1. ERISA and *Gobeille*.

 The Employee Retirement Income Security Act of 1974 (“ERISA”) [[9]](#footnote-9) is a comprehensive statutory scheme that governs employee benefit plans. The statute was enacted in response to concerns about “the mismanagement of funds accumulated to finance employee benefits and the failure to pay employees benefits from accumulated funds”. *See Carpenters Local Union v. United States Fidelity & Guaranty,* 215 F.3d 136 (1st Cir. 2000), quoting *Massachusetts v. Morash,* 490 U.S.107, 115, 104 L.Ed. 98, 109 S.Ct.1668 (U.S. 1989). Section 514 (a) of ERISA [[10]](#footnote-10) provides that the Act “shall supersede any and all State laws insofar as they…relate to any employee benefit plan” covered by the statute (the “pre-emption” clause”).

 Nevertheless, the ERISA preemption of state legislation does not apply to “any law of any State which regulates insurance”. *Codified at* *29 U.S.C.§ 1144(b)(2)(A).* This provision is commonly referred to as the ERISA “saving clause,” which, in effect, permits states to enforce their insurance laws subject to the limitations of the “deemer clause.”

 Under the “deemer clause,” 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, (1990).In essence, the deemer clause exempts self-insured employee benefit plans from state laws that regulate insurance.

The Supreme Court has determined that Congress intended Section 514 to establish the regulation of employee welfare benefit plans “as exclusively a federal concern” *Alessi v. Raybestos-Manhattan, Inc.,* 451 U.S. 504, 523, 68 L.Ed. 402, 101 S.Ct. 1895 (U.S.1981). In providing for the preemption of state legislation relating to ERISA governed employee benefit plans, Congress intended:

to ensure that plans and plan sponsors would be subject to a uniform body of benefits law; the goal was to minimize the administrative and financial burden of complying with conflicting directives among States or between States and the Federal Government…[and to prevent] the potential for conflict in substantive law…requiring the tailoring of plans and employer conduct to the peculiarities of the law of each jurisdiction. *Ingersoll-Rand Co. v. McClendon,* 498 U.S. 133, 141, 112 L.Ed. 2d 474, 111 S.Ct. 478 (U.S. 1990).

The comprehensive regulation of employee welfare and pension benefit plans under ERISA extends to those that provide “medical, surgical, or hospital care or benefits” for plan participants or their beneficiaries through the purchase of insurance or otherwise. *See 29 U.S.C. § 1002(1).* Accordingly, the Act controls the administration of benefit plans by imposing reporting and disclosure requirements, *29 U.S.C. §§ 101-111;* participation and vesting requirements, *§§ 201-211;* funding standards, *§§ 301-308;* and fiduciary responsibilities for plan administrators, *§§ 401-414.*

Initially, the courts interpreted the ERISA preemption clause rather broadly. *See Shaw v. Delta Air Lines, Inc.,* 463 U.S. 85, 77 L.Ed. 490, 103 S.Ct. 2890 (U.S. 1983); *District of Columbia v.Greater Washington Bd. of Trade,* 506 U.S. 125, 121 L.Ed. 2d 513, 113 S.Ct.580 (U.S. 1990). In *Shaw* the Supreme Court interpreted the phrase “a law ‘relates to’ an employee benefit plan” to mean “if it has a connection with or reference to such a plan” and held state statutes meeting this standard to be preempted by ERISA. *463 U.S. 85 at 96-97.*

In the mid-1990s, the Supreme Court adopted a more deferential position with respect to state statutes of general application that indirectly relate to the administration of employee benefit plans governed by ERISA. In *New York State Conference of Blue Cross and Blue Shield Plans v. Travelers Insurance Co.,* 514 U.S. 645, 115 S.Ct. 1671, 131 L.Ed. 2d 695 (U.S. 1995) the Supreme Court rejected an ERISA preemption challenge to a state hospital regulatory statute that imposed surcharges upon commercially insured patients and health maintenance organizations. New York State had adopted a hospital surcharge applicable to commercial insurers and HMOs designed to foster hospital cost containment and promote health care for the uninsured and underinsured. An ERISA governed employee benefit plan that operated hospitals subject to the statutory surcharge challenged the statute on the grounds the surcharge would increase the costs of insuring hospital services for plan members, thus triggering the ERISA preemption. The rationale underlying that position was that the increased hospital charges interfered with the health plan’s ability to select coverage for its members.

The Court observes that “the basic thrust of the preemption clause was to avoid a multiplicity of regulation in order to permit the nationally uniform administration of employee benefit plans.” The Court found that the New York statute did not “relate to” the employee benefit plan within the meaning of Section 514 (a), since it had only an indirect economic influence upon choices made by insurance purchasers, including ERISA plans. The Court further found that an indirect economic influence does not bind plan administrators to any particular choice or preclude uniform administrative practice or the provision of a uniform interstate benefit package. Rather, it simply bears on the costs of benefits and the relative costs of competing insurance available to such plans. In concluding that the ERISA preemption was not designed to promote cost uniformity amongst health plans, the Court ruled: “…preemption does not occur if the state law has only a tenuous, remote or peripheral connection with covered plans, as is the case with many laws of general applicability.” [citation omitted] *Travelers, 514 U.S. 645, 661.*

 The reasoning according the ERISA preemption a more narrow construction is based, to a significant extent, upon a more deferential approach to subject areas which have “been traditionally occupied by the States.” *See, e.g. Jones v. Rath Packing Co.,* 430 U.S.519, 525 (U.S. 1977). In *De Buono v. NYSA-ILA Medical and Clinical Services Fund,* 520 U.S. 806, (U.S. 1997), the Supreme Court, rejected an ERISA challenge to a New York statute which imposed a gross receipts tax upon ERISA funded medical centers. The *De Buono* Court concluded that because the purpose of the statute was not to regulate any aspect of ERISA governed plans, and the statute did not expressly refer to ERISA or ERISA governed plans, the Court the impact of the tax upon ERISA plans was only indirect and, hence, not subject to the ERISA preemption clause. *De Bueno, 520 U.S. 806 at 816.*  The Court observed:

Any state tax, or other law, that increases the cost of providing benefits to covered employees will have some effect on the administration of ERISA plans, but that simply cannot mean that every state law with such an effect is preempted by the federal statute.*520 U.S. 806 at 816.* [[11]](#footnote-11)

 VII. *Gobeille v. Liberty Mutual Insurance Co*.,

 In the 2016 case of *Gobeille v. Liberty Mutual Insurance Co*., the pendulum has swung back to a more sweeping approach to pre-emption. By a 6-2 vote, the Court held that ERISA preempts, as applied to ERISA plans, a Vermont law that requires healthcare payers to provide claims data and related information to a state healthcare database that helps the state assess the cost and effectiveness of health care services.

 Liberty Mutual Insurance Company operates a self-insured health plan that provides benefits to its employees and their families and qualifies as an ERISA plan. Blue Cross Blue Shield of Massachusetts is its third-party administrator, and was required under the Vermont law to report information about Liberty Mutual’s Vermont plan members. In 2011, Vermont issued a subpoena ordering Blue Cross to transmit files on member eligibility and health care claims for its Vermont members. Liberty Mutual, however, instructed Blue Cross not to comply. Liberty Mutual then filed an action in federal district court seeking declaratory and injunctive relief on the ground that ERISA preempts application of Vermont’s statute to its health plan.

 The US District Court ruled for Vermont, but the Second Circuit reversed, holding that ERISA preempts Vermont’s law. In an opinion by Justice Kennedy, the Supreme Court affirmed. ERISA’s preemption clause preempts “any and all State laws insofar as they may now or hereafter relate to any employee health plan.” 29 U.S.C. §1144(a). The Court explained that its case law interpreting the clause recognizes two categories of state laws that are preempted: a state law that has a “reference to” ERISA plans, and a state law that has an impermissible “connection with” ERISA plans, meaning the law “governs . . . a central matter of plan administration” or “interferes with nationally uniform plan administration” (internal quotation marks omitted).

 The Court concluded that Vermont’s law fell within the second category of ERISA-preempted state laws by governing a core aspect of ERISA regulation: reporting by ERISA plans. The Court explained that ERISA mandates oversight systems and procedures for employer health plans that are intended “to be uniform.” In particular, ERISA plans “must file an annual report with the Secretary of Labor” that includes financial information; and “[b]ecause welfare benefit plans are in the business of providing benefits to plan participants, a plan’s reporting of data on disbursements by definition incorporates paid claims.” Also, “plans must keep detailed records” in connection with those reports. The Court reasoned that all of this shows that “reporting, disclosure, and recordkeeping are central to, and an essential part of, the uniform system of plan administration contemplated by ERISA.”

 This led to the Court’s critical conclusion: “Vermont’s reporting regime, which compels plans to report detailed information about claims and plan members, both intrudes upon “a central matter of plan administration” and “interferes with nationally uniform plan administration.” “The law,” the Court stated, “govern[s] plan reporting, disclosure, and — by necessary implication — recordkeeping….” “Differing, or even parallel, regulations from multiple jurisdictions could create wasteful administrative costs and threaten to subject plans to wide-ranging liability.” The Court concluded that “[p]re-emption is necessary to prevent the States from imposing novel, inconsistent, and burdensome reporting requirements on plans.”

 Justices Thomas and Breyer each authored a concurring opinion. Justice Thomas questioned whether ERISA‟s preemption clause is a valid exercise of congressional power under Article I of the Constitution, given that the clause’s text allows for preemption of “a wide array of state laws” that “have nothing to do with interstate commerce.” In other words, Justice Thomas suggested the pre-emption clause violates the Constitution.

 Justice Breyer wrote to emphasize that a failure to find preemption could subject ERISA health plans “to 50 or more potentially conflicting information reporting requirements.” But he added that “the Secretary of Labor could . . . develop reporting requirements that satisfy the States’ needs.”

 Justices Ginsburg issued a dissenting opinion, which Justice Sotomayor joined. In her view, “Vermont’s effort to track health care services provided to its residents and the cost of those services does not impermissibly intrude on ERISA’s dominion over employee benefit plans.” ERISA does not preempt Vermont’s law, Justice Ginsburg concluded, because the law and ERISA’s objectives serve different purposes. ERISA’s domain is geared toward the vesting of benefits, claims processing, and beneficiary designations. Vermont’s law, by contrast, aims to improve health care quality and utilization and reduce costs by analyzing comprehensive health care data. She also concluded that Liberty Mutual failed to show that Vermont’s law would impose significant costs on ERISA plans. And even if data-collection laws are not uniform among the states, “state-law diversity is a hallmark of our political system and has been lauded in this Court’s opinions.”[[12]](#footnote-12)

 Many issues and questions arise from the decision in *Gobeille*. For one, the decision did not strike down APCD laws in Vermont or anywhere else. Unlike the *IMS Health Inc.* case, no law was declared unconstitutional. All of MHDO’s statutes remain “on the books.” TPAs and insurance carriers remain subject to them, as do governmental health plans, even if self-insured. In addition, the case regarded self-insured ERISA plans; and is only definitive regarding self-insured ERISA plans. Also, some employers (generally larger) have indicated they may want to continue to submit data, since they are Superusers of the data.

 Since a primary objective and purpose of MHDO is “to create and maintain a **useful, objective, reliable and comprehensive health information database** that is used to improve the health of Maine citizens and to issue reports, as provided in section 8712…” 22 MRS §8703, the MHDO and Board are obligated, and have agreed, to pursue efforts to ensure the data MHDO collects is as reliable, objective and comprehensive as feasible. So the efforts of the MHDO should continue to be directed towards:

* constructing a simple means for self-insured employers to opt in or voluntarily submit data if they want to (in recognition that even if not legally required, entities can still report under HIPAA as APCDs are health oversight agencies. (45 CFR §§164.501; 164.512 (d)).
* taking a position against expanding the *Gobeille* holding beyond self-insured employers; some insurers are evaluating arguments whether *Gobeille* extends to insured plans; MHDO can consider countering with idea such as New Hampshire is pursuing - emphasizing that their APCD is in their bureau of insurance and protected by the ERISA savings clause; and
* monitoring and participating in efforts with the federal government (Departments of Labor) on the “Justice Breyer option” to consider a consistent set of data reporting to be required at the federal level, covering some or all ERISA health plans, as the APCD Council described.
1. Some of this explanation was taken from the Wikipedia article “Law of the United States.” I also relied heavily on Paul Gauvreau’ s “Maine Health Data Organization: A Legislative History.” [↑](#footnote-ref-1)
2. Incidentally, if you see a reference to the Maine statutes as MRS*A*, the A stands for annotated, which signifies the version of the Maine Revised Statutes published by West Publishing Company. [↑](#footnote-ref-2)
3. On the SOS webpage go to Online Services then State Agency Rules. [↑](#footnote-ref-3)
4. *See 121st Maine Legislature, First Regular Session, L.D. 1611, “An Act to Provide Affordable Health Insurance to Small Businesses and Individuals and to Control Health Care,” P.L. 2003, c. 469.* [↑](#footnote-ref-4)
5. *See P.L. 2003, c. 469, §C-28, codified at 22 M.R.S.A. §8708-A.*  [↑](#footnote-ref-5)
6. *See 22 M.R.S.A. §8708-A. See also, 24-A MRS §§6951 (Maine Quality Forum); and 6952(Maine Quality Forum Advisory Council).* [↑](#footnote-ref-6)
7. *P.L. 1999, c. 353, §9.*  [↑](#footnote-ref-7)
8. *P.L. 2001, c. 457, §14.*  [↑](#footnote-ref-8)
9. ERISA is codified at *29 U.S.C.§§ 1001-1461.* [↑](#footnote-ref-9)
10. Section 514(a) has been codified at *29 U.S.C. 1144(a).* [↑](#footnote-ref-10)
11. From a Paul Gauvreau memo dated 2002. [↑](#footnote-ref-11)
12. From a National Association of Attorneys General (NAAG) Supreme Court Report, Vol. 23, Issue 7 March 16, 2016. [↑](#footnote-ref-12)