# MAINE HEALTH DATA ORGANIZATION:

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

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I. The Purpose of Maine Health Data Organization[[1]](#footnote-1)

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 regarding MHDO are in 22 MRS Chapter 1683 (§§8701-8713). The sections 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 many requirements of the board, but also gives it some broad authority and power to go beyond what the legislature requires. 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 and 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.[[2]](#footnote-2) 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.

In the Dirigo Health legislation, the MHDO Board was directed to adopt rules regarding the collection of quality data. [[3]](#footnote-3) The MHDO Board was required to work with the Maine Quality Forum and Maine Quality Forum Advisory Council in the development of these rules. [[4]](#footnote-4) 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 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 the reports required by 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.”[[5]](#footnote-5) 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.[[6]](#footnote-6)

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 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 system**s.**  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”) [[7]](#footnote-7) 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). Section 514 (a) of ERISA [[8]](#footnote-8) 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).* 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.*

In the 2016 case of *Gobeille v. Liberty Mutual Insurance Co*.,[[9]](#footnote-9) 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.

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 to pursue efforts to ensure the data MHDO collects is as reliable, objective, and comprehensive as feasible. Since *Gobeille* the efforts of the MHDO have been directed toward keeping the database as **comprehensive** as feasible by:

* 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)); resulting in changes to Chapter 243.
* participating in efforts with NAHDO and the APCD Council the federal government (Departments of Labor) on the “Justice Breyer option” of establishing a consistent set of data reporting (common data layout) to be required at the federal level, covering some or all ERISA health plans, as described.

1. MORE ON QUALITY AND PRICE TRANSPARENCY

Price transparency laws tend to clarify pricing disparity between providers, within providers for different payers, and between commercial payers. Because the purpose of price transparency provisions is to hold down the price of health care, and hence health insurance costs, they can be unpopular with both providers and payers. Recently data submitters to MHDO have questioned the antitrust implications of such pricing clarity.

The purposes of MHDO 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. 22 MRS §§8703(1). MHDO is charged with promoting public transparency of the quality and cost of health care in Maine. 22 MRS §§8712. The reports mandated by §8712, include reports on “payments for services rendered by health care facilities and practitioners to residents of the state…” 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.”

Thus Maine’s law requires that prices paid by individual commercial carriers for services rendered by healthcare facilities and practitioners to residents of the state be made publicly available.[[10]](#footnote-10) In the recent past payers have suggested that making granular payment data available to providers may create antitrust issues. When businesses restrict competition by agreeing to fix prices, allocating markets, or engaging in other anticompetitive activity, the benefits of competition (lower prices and increased quality of products and services) erode. Federal antitrust/unfair trade laws forbid and punish this kind of anti-competitive behavior.[[11]](#footnote-11) Maine has its own antitrust and unfair trade practices laws, which are modeled on federal statutes. It is essential to remember however, that illegal behavior requires an agreement to engage in anticompetitive behavior.

Antitrust problems arise when exchange of pricing information is used as part of an agreement or understanding to influence prices. Most information exchanges are competitively neutral or even pro-competitive. Benefits include that it allows consumers to better shop by price and gets competitors to compete on price. As one commentator said it is hard to compete on price if you do not know what a competitor’s price is. Also, price transparency may have a self-auditing effect when competitors see how well others are performing.

* **Payments.** While payers have questioned the antitrust implications of sharing releasing certain data elements, it is clear the trend of pricing transparency will continue. Maine law clearly mandates it, and so efforts towards ensuring that alternative payment or reimbursement models are captured in the data need to be explored.
* In addition we hear more and more about the issue of **quality** in health care. As described above, the information on quality reporting in Sections 8712(1) calls for more complex analysis of health care outcomes. Another effort going forward will be the return to consideration of whether more clinical data should be defined and collected. As with payment information, clinical data that supports assessment of the quality of health care services, their outcomes, and the effectiveness of those services, is required by Sections 8703(1) and 8712(1).

APPENDIX A: A Bit About Reading the Law[[12]](#footnote-12)

**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. 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. Though federal law is supposed to be limited to certain areas, the federal government regularly relies on 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.[[13]](#footnote-13)

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.

Maine’s Secretary of State publishes adopted rules in the Code of Maine Rules (“CMR”).[[14]](#footnote-14) 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.** Judges interpret the law. 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 several 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 included 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 argued that 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 from enforcing the new law. The First Circuit found the law *was* constitutional concluding that it regulated conduct not speech, and 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]. IMS 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, the Maine legislature enacted PL 2011, c. 494 “An Act to Conform Maine’s Prescription Drug Privacy Laws with the United States Constitution,” which 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.

APPENDIX B: More Detail -*Gobeille v. Liberty Mutual Insurance Co*.,

Initially, the courts interpreted the ERISA preemption clause rather broadly. [[15]](#footnote-15) *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.

The Court observed 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. 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). For example, 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 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.*

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 arguing 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.” 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” supporting 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.”

Justice Breyer wrote a concurring opinion 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.”

APPENDIX C: Payments, Antitrust, Secrecy, and Transparency

Price transparency in health care is a recent innovation in the US. Maine has been a leader in APCD data collection and price transparency, but has only been collecting payment data since 2003, and making it public in a user-friendly format for a few years. In contrast, antitrust laws have been enforced on the federal level since the 1890s. This was before health insurance existed, physicians gained professional status, and hospitals could provide reliable treatment.

Antitrust laws are designed to protect and encourage open competition between businesses or sellers of any product or service. Competition provides a powerful incentive for businesses to find ways to increase efficiency, lower prices and improve the quality of their products or services. **In a healthy competitive marketplace, consumers have the widest choice of products and services at the lowest prices.** The corollary for businesses in a competitive market is generally less profit per unit or service sold. Thus for businesses there is constant friction between maximizing profits and being competitive by offering consumers the best products at the lowest price.

When businesses restrict competition by agreeing to fix prices, allocating markets, or engaging in other anticompetitive activity, the benefits of competition (lower prices and increased quality of products and services) erode. Federal antitrust/unfair trade laws forbid and punish this kind of anti-competitive behavior. Maine has its own antitrust and unfair trade practices laws, which are modeled on federal statutes. Maine’s antitrust laws prohibit:

1. Contracts, combinations or conspiracies in restraint of trade;
2. Monopolization offenses;
3. Mergers and acquisitions which tend to substantially reduce competition; and
4. Unfair methods of competition, as well as unfair acts and practices in the conduct of trade or commerce.

Maine’s Monopolies and Profiteering Act (10 MRS Chapter 201, §§1101-1110) governs the first three and our Unfair Trade Practices Act (5 MRS Chapter 10, §§205-A-214) governs the fourth. These laws cover the health care industry. The AG’s Office has brought several actions involving provider mergers, price fixing, market allocation, and “concerted refusal to deal.” At the federal level the Department of Justice (“DOJ”) and the Federal Trade Commission (“FTC”) enforce antitrust laws. These agencies pursue cases like those the state acts on. In addition the FTC reviews state actions and legislation to assess whether they think it will help or hinder competition.

Some activities by competitors are deemed so harmful that they are considered per se violations – it does not matter whether the activities have a harmful effect on competition; the effect is presumed. These generally include price fixing, allocation of customers, markets or territories, bid-rigging, and some forms of boycotts. However, there must be an agreement (contract, combination, or conspiracy) involved. So, even for price-fixing, tacit conduct is not enough to prove an antitrust violation. *See, e.g., In re: Text Messaging Antitrust Litigation,* 782 F.3d 867 (7th Cir. 2015).

Problems arise when exchange of pricing information is used as part of an agreement or understanding to influence prices. Most information exchanges are competitively neutral or even pro-competitive. Benefits include that it allows consumers to better shop by price and gets competitors to compete on price. As one commentator said it is hard to compete on price if you do not know what a competitor’s price is. Also, price transparency may have a self-auditing effect when competitors see how well others are performing.

Risks include potential collusion on prices. It could make it simpler for competitors to communicate about mutually acceptable levels of pricing. Of course, as discussed above, there would have to be an agreement made by the competitors to make it illegal. Even without overt price-fixing or illegal conduct price transparency may lead to price uniformity at the highest level. (i.e. tacit collusion). While this would be unfortunate, it is not illegal. Ironically, any tacit collusion would likely appear in the MHDO data and on the price compare website.

In 1996, the DOJ and FTC issued the Statements of Antitrust Enforcement Policy in Health Care. These statements are aimed at providers. Statement 6 (Provider Participation In Exchanges Of Price and Cost Information) applies to prices charged and compensation paid by health providers. All the Statements in this policy had to do with joint *provider* activity which was rapidly developing at that time. The feds noted both good and bad potential:

“Participation by competing providers in surveys of prices for health care services, or surveys of salaries, wages or benefits of personnel, does not necessarily raise antitrust concerns. In fact, such surveys can have significant benefits for health care consumers. Providers can use information derived from price and compensation surveys to price their services more competitively and to offer compensation that attracts highly qualified personnel. Purchasers can use price survey information to make more informed decisions when buying health care services. Without appropriate safeguards, however, information exchanges among competing providers may facilitate collusion or otherwise reduce competition on prices or compensation, resulting in increased prices, or reduced quality and availability of health care services. A collusive restriction on the compensation paid to health care employees, for example, could adversely affect the availability of health care personnel.”

In most of those 9 statements, the USDOJ and FTC gave health care providers guidance in the form of antitrust “safety zones.” These safety zones describe conduct (of the providers) that the enforcement agencies “will not challenge under the antitrust laws, absent extraordinary circumstances.” The agencies specifically note in the introduction “some parties have interpreted the safety zones as defining the limits of joint conduct that is permissible under the antitrust laws. This view is incorrect.” Thus even for information amongst providers, these criteria do not “forbid” information exchanges that fall outside these parameters. For Statement 6 the Safe Harbor should meet the following criteria:

(1) managed by a third-party

(2) based on data more than 3 months old; and

(3) at least five providers reporting data, no individual provider’s data represents more than 25 percent on a weighted basis of that sta­tistic, and any information disseminated is sufficiently aggregated such that it would not allow recipients to identify the prices charged or compensation paid by any one provider.

These policy statements are just that – policy –not requirements. As discussed above the Maine legislature has made its own policy statement on price transparency and the MHDO by the requirements in sections 8703 and 8712. The federal policy does not forbid or limit MHDO’s data releases.

MHDO AND STATE IMMUNITY DOCTRINE

As a general matter, state activities are not subject to state or federal anti-trust review, anyway. The states can and do make laws that have some anti-competitive effects to achieve what a state may believe is a greater good. Under the US Supreme Court decision in *Parker v. Brown*, 317 US 341 (1943), state and municipal authorities are exempt from federal antitrust lawsuits. This immunity covers action taken pursuant to a clearly expressed state policy. When a state approves and regulates certain conduct, even if it is anticompetitive, or potentially anticompetitive under FTC or DOJ standards, the federal government must respect the decision of the state. [[16]](#footnote-16)

MHDO as an independent state agency is protected under this doctrine. This doctrine can also apply to provide immunity to non-state actors, such as MHDO Board members if a two-pronged test is met: (1) the challenged conduct/restraint is clearly articulated and affirmatively expressed as state policy; and 2) there must be active supervision by the state of the policy or activity.[[17]](#footnote-17) *North Carolina State Bd. of Dental Examiners v. FTC,* 574 US \_\_\_(2015).

In Maine, price transparency is a stated purpose of the MHDO. 22 MRS §8712. The MHDO advances clearly articulated policies to collect data on prices and make that available on its public website, and to anyone who requests it and meets all of the many conditions of Chapter 120.

The MHDO Board supervises the activity of the MHDO, but unlike “self-regulating” professional Boards, this Board is evenly split between providers (sellers) and payers (buyers). The MHDO Board consists of 9 provider seats and 9 payer seats (4 consumers, 3 employers, 2 third-party payers). In addition there is 1 designee of DHHS, and 1 designee of Dirigo Health. Finally, there is a designee of DPFR, who does not vote and serves in a consultative capacity. The MHDO is advised by the Attorney General, a separate state agency. 22 MRS §8703(5). Its Data Release Rules, Chapter 120, are major-substantive, meaning there is the opportunity for legislative review before they became effective. So there is active supervision by the state.

MHDO board members are also entitled to tort immunity under the Maine Tort Claims Act (“MTCA”), 14 M.R.S. Ch. 741.  The MTCA includes board members within the definition of state employees covered by the Act.  Section 8102(1) defines “employee” to include any person acting on behalf of a governmental entity in any official capacity, whether compensated or not.  The term “governmental entity” includes the State. 14 MRS §8102(2).  The term “State” includes boards and commissions. 14 M.R.S. §8102(4).  Thus, MHDO Board members are entitled to all of the immunities under the MTCA, and generally the State would provide a legal defense for any tort claims arising against board members. 14 M.R.S. §§8111; 8112. These protections apply so long as MVB members are acting within the course and scope of their employment and not acting in bad faith. 14 M.R.S. §8112(1)-(3).

The MTCA also limits personal liability of any board member for negligent acts or omissions to $10,000, and the state would pay that amount so long as Board members were acting within the scope of their work on the Board. 14 M.R.S. §8104-D.

Although it may be overdoing it, the MHDO will add an indemnification clause to the MHDO DUA saying that the data recipient will indemnify MHDO for any liability that may result from the recipient’s violation of law.  MHDO has also agreed to include a Provision that reminds the data recipient that misuse of the MHDO released data for anti-competitive behavior such as collusion on price is a violation of law. The MHDO will report any such violation in the use of its data to the appropriate authorities.

TRADE SECRETS/CONFIDENTIAL INFORMATION

Another claim sometimes made by payers is that certain data elements are trade secrets. Maine law says:

"Trade secret" means information, including, but not limited to, a formula, pattern, compilation, program, device, method, technique, or process, that:

A. Derives independent economic value, actual or potential, from not being generally known to and not being readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use; and

B. Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.” 10 MRS §1542(4). An entity asserting the argument would have to meet this standard in court to get an injunction preventing such a release. Data submitters are given time to pursue such a course, before MHDO releases data that has been objected too.

1. Some of this is from Paul Gauvreau’ s “Maine Health Data Organization: A Legislative History.” There is also a longer piece about reading the law at Appendix A. [↑](#footnote-ref-1)
2. *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-2)
3. *See P.L. 2003, c. 469, §C-28, codified at 22 M.R.S.A. §8708-A.*  [↑](#footnote-ref-3)
4. *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-4)
5. *P.L. 1999, c. 353, §9.*  [↑](#footnote-ref-5)
6. *P.L. 2001, c. 457, §14.*  [↑](#footnote-ref-6)
7. ERISA is codified at *29 U.S.C.§§ 1001-1461.* [↑](#footnote-ref-7)
8. Section 514(a) has been codified at *29 U.S.C. 1144(a).* [↑](#footnote-ref-8)
9. There is more about this case in Appendix B. [↑](#footnote-ref-9)
10. This statute is in accord with other price transparency efforts. 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, 24 MRS §2987 (which has since been updated and moved to 22 MRS §1718-A) makes similar requirements of health care practitioners for prices the practitioner charges clients directly when there is no insurance coverage, or coverage is denied. [↑](#footnote-ref-10)
11. There is more on antitrust in Appendix C. [↑](#footnote-ref-11)
12. 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-12)
13. 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-13)
14. On the SOS webpage go to Online Services then State Agency Rules. [↑](#footnote-ref-14)
15. The first half of this Appendix is from a Paul Gauvreau memo dated 2002. [↑](#footnote-ref-15)
16. Taken from [https://www.law.cornell.edu/wex/state­\_action\_antitrust\_immunity](https://www.law.cornell.edu/wex/state_action_antitrust_immunity) and Wikipedia on Parker immunity doctrine. [↑](#footnote-ref-16)
17. For another example Maine has the Hospital and Health Care Providers Cooperation Act (22 MRS Chapter 405-A). “The Legislature finds that it is necessary and appropriate to encourage hospitals and other health care providers to cooperate and enter into agreements that will facilitate cost containment, improve quality of care and increase access to health care services. This Act provides processes for state review of overall public benefit, for approval through certificates of public advantage and for continuing supervision. It is the intent of the Legislature that a certificate of public advantage approved under this chapter provide[s] state action immunity under applicable federal antitrust laws.” 22 MRS §1842. [↑](#footnote-ref-17)