

**MAINE HEALTH DATA ORGANIZATION:
Law, History, Purpose, Powers and Duties
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I. A Bit About Reading the Law¹

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 enactments regarding powers set out in the constitution. These include borrowing money, regulating commerce, coining money, establishing post offices and roads, granting copyrights and patents, etc. These are items that tend to affect the entire country. In actuality, the federal government regularly uses the interstate commerce clause to regulate in just about any area you can think of.

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 levels of government 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 sections 1320(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 you worked on last legislative session was LD 1740 "An Act to Amend the Laws Relating to Health Care Data." When that Act was approved by the

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."

Governor and became law it became Public Law (“PL”) 2013, Chapter 528. Unlike federal Acts, Maine LDs give not only the section numbers for the LD, but note the title and sections of the Maine Revised Statutes (“MRS”) where the changes and additions will be codified.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 that anyone reading it knows when it was enacted or amended, and the chapter of public law that contains the language. 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 denotes those rules 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 gets 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 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 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.

² Incidentally, if you see a reference to the Maine statutes as MRSA, the A stands for annotated, which signifies the version of the Maine Revised Statutes published by West Publishing Company.

³ On the SOS webpage go to Online Services then State Agency Rules.

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, around 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, which 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. ...

III. Requirements of the Maine Health Data Organization

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, in the beginning the MHDO took over for the MHCFC. They also initially took over the data that had been collected by MHCFC. In the first few years of MHDO's existence they were also 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."

IV. Claims Data

In 2001, “An Act to Create the Maine Health Data Processing Center,” was enacted. PL 2001, c.456, in conjunction with the creation of the MHDPC, focused MHDO on a new role: collection and processing of “health care claims data...” 10 MRS §681. The function of the MHDPC included establishing, maintaining and making available to the MHDO “an all-payor and all-setting health care database system based on claims data in addition to the existing databases of the MHDO. The center shall provide the MHDO with a health care claims database for public dissemination, subject to confidentiality requirements of Title 22, chapter 1683 and the rules adopted pursuant to the chapter, within the time period and in the manner specified by the MHDO...” 10 MRS §682.

The related rules are at 90-590 CMR Chapter 243, “Uniform Reporting System for Health Care Claims Data Sets.” In addition, 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).⁴

V. Quality Data and Price Transparency

In 2003 the Legislature significantly expanded the data gathering and reporting responsibilities of the MHDO when it approved Governor Baldacci’s Dirigo Health legislation.⁵ 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); and 22 MRS §8712 requiring MHDO to produce “clearly labeled and easy-to-understand” reports. Whereas the MHDO was responsible since its inception for the submission of an annual report to the Governor and Legislature regarding the operation of the Organization and health care trends,⁶ the MHDO is now required to produce “clearly labeled and easy-to-understand reports”, to be 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.⁷ The MHDO Board was required to work with the Maine Quality Forum and Maine Quality Forum Advisory Council in the development of these rules.⁸ 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

⁴ The MHDPC is no longer functioning since the data processing roles have been taken on by MHDO.

⁵ 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.

⁶ See P.L. 1995, c. 653, codified at 22 M.R.S.A. §8704(7).

⁷ See P.L. 2003, c. 469, §C-28, codified at 22 M.R.S.A. §8708-A.

⁸ See 22 M.R.S.A. §8708-A. See also, 24-A MRS §§6951 (Maine Quality Forum); and 6952 (Maine Quality Forum Advisory Council).

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 analysis of the data and presentation of the 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.

VI. Other Requirements.

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.”⁹ 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 identify 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

⁹ P.L. 1999, c. 353, §9.

2013 c. 528). In 2001 the Legislature designated the public access rules to be major substantive rules, subject to the review and approval of the Legislature.¹⁰

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. With that, we can turn from requirements that are made of MHDO Board by the law, and consider the powers and authority the law gives the Board.

VII. Authority of the Maine Health Data Organization

In addition to the numerous requirements the MHDO has to fulfill, it is authorized or has the power to do even more. These powers include both executive type powers, to keep the organization functioning. MHDO also has 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, or enforce state laws. There is more about these general powers in your own statute. Under **§8704**. The board has the following powers and duties....

- The organization may modify the uniform reporting systems for clinical, financial, quality and restructuring data to allow for differences in the scope or type of services and in financial structure among health care facilities, providers or payors subject to this chapter.
- The board may provide analysis of data upon request....
- **Contracts for data collection; processing.** The board may contract with one or more qualified, nongovernmental, independent 3rd parties for services necessary to carry out the data collection, processing and storage activities required under this chapter....
- **Public hearings.** The board may conduct any public hearings determined necessary to carry out its responsibilities. ...
- **Grants.** The board may solicit, receive and accept grants, funds or anything of value from any public or private organization ...
- **Cooperation; advice.** The board may cooperate with and advise the department and any other person or entity on behavioral risk factor surveys, work site health and safety, and health work force research....
- **Other powers.** The board may exercise all powers reasonably necessary to carry out the powers expressly granted and responsibilities expressly imposed by this chapter.

¹⁰ P.L. 2001, c. 457, §14.

Finally, the statute includes a few broad substantive, authorizations for MHDO to collect more health 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). Note also that the rules on Release of Data to the Public defines “Clinical Data” to mean health care claims, hospital, non-hospital health care facility, quality data, and all other data as described in 22 MRS §§ 8708, 8708-A, and 8711. 90-590 CMR Chapter 120, Section 2(B). So, the statutes and rules do not make any clear distinctions between what are commonly considered administrative data, claims related data, and clinical outcomes/results/effectiveness data.

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).]”