

Report of the LD 1818 Work Group

***To Evaluate Options and Actions Available
to Improve the Availability Of and Access To
Health Care Data and to Examine
the All-payor Claims Database system in Maine***

Submitted to: the 126th Maine State Legislature

February 23, 2013

Working Group on LD 1818

February 23, 2013

Final Report: Resolve Chapter 109 (2011), Resolve to Evaluate the All Payer Claims Database of the State

Senator Craven, Representative Farnsworth, and members of the Joint Committee on Health and Human Services:

As chairs of the working group convened under Resolve Chapter 109 (2011), Resolve to Evaluate the All Payer Claims Database of the State, we are pleased to present you with the working group's report on health care data in Maine. The report is the product of a diverse multi-stakeholder group in which all sectors of Maine's health care industry and customers were represented. The Report is a consensus statement of the group which consisted of 17 diverse interests and input from more than 90 stakeholders, representing individual customers, payers, insurers, providers, businesses, public and private entities, health care information organizations, and others.

It is important to note that the term "consensus" reflects what may be called the lowest common denominator--the most basic level of opinion among this group of people.

Some members viewed the report as a "floor" and wanted the report to be more strident in its recommendations, while others a "ceiling." (Attached to this report are comments on both ends of the spectrum.)

We believe that the report will serve you and future Legislators as a current description of Maine's health data structures and as a summary of the future uses and expectations of these data in policy formulation, health system improvement, and public awareness.

It has been a privilege to work on this report. We look forward to discussing it with you.

Colin McHugh

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I. Executive Summary

The judicious use of health care data collected through our insurance, clinical care, and other systems offers the potential for a smarter health care system in Maine's future: one in which doctors know the best practice treatments, patients know the most effective health providers, insurers and government know how to create financial incentives for cost-effective care.

Maine is ahead of other states in its use of health care data. But the further we go along this road, the more complicated the issues become. This report is the result of a multi-stakeholder collaborative effort established by a Legislative Resolve to "improve the availability and access to health care data." The Resolve identified four areas for evaluation related to: the current structure of the Maine Health Data Organization (MHDO); the current uses of health care data; changes needed to increase access to health care data; and the most appropriate and cost-effective sources of data.

The multi-stakeholder group worked tirelessly over the past year to produce this consensus report. It provides a comprehensive and thorough review of the current state of health care data issues in Maine, as well as the beginnings of a road map for future initiatives. The report concludes with six recommendations:

1. Continue the ongoing work of the MHDO Board to implement its new vision and business imperatives;
2. Charge the MHDO to lead an effort to recommend solutions for improved efficiency for current data submitters, and to identify standards to link various health care databases;

3. Continue the pilot between MHDO and HealthInfoNet to determine the feasibility of linking administrative claims and clinical data at an affordable cost;
4. Conduct a collaborative strategic examination on the health care data currently collected, and identify sustainable business models that are efficient, avoid fragmentation and duplication, provide the best value for data, and identify the best uses of data;
5. Have the MHDO and Maine's Office of the State Coordinator for HIT collaborate to leverage funding available for electronic health records, access to health care data, and reporting systems in order to improve the efficiency and quality of health care; and
6. Continue the work of the Maine Quality Forum (MQF) within the MHDO (conditioned on availability of funding and the identification of administrative efficiencies).

II. Introduction from the Chairs

The cost of health care is having a stifling effect on Maine's workers, families, taxpayers, and the economy. Public and private health care costs continue to grow more rapidly than those in other sectors. These obligations are crowding out our capacity to invest in other public goods, such as education and infrastructure, and to grow our economy.

The health care system in the United States, and in Maine, is less efficient than those in other developed countries. If we could achieve the efficiency of those health systems – or even in the best systems within in the United States – we could eventually lower health costs by 15% to 30% in Maine, with no sacrifice in quality.

In order to accomplish this efficiency, our health system needs the capability to observe and measure its *value* (defined as favorable outcome achieved per dollar spent); to become, as the Institute of Medicine has described, a *continuously learning health system*. This capability can only be achieved through the judicious and widespread use of health data.

Maine is ahead of most states in its ability to analyze the performance of the health care system, based on the health data we currently collect. However, there is considerable room for improvement. This report, the product of a multi-stakeholder workgroup created through *Resolve Chapter 109 (2011), Resolve to Evaluate the All-Payer Claims Data System for the State (Resolve)*, explores the current state of health data arrangements in Maine and makes recommendations for continued improvement.

The State of Maine has been a leader in the collection of health data to facilitate analysis of the state health care costs. The Maine Health Data Organization (MHDO), a state agency, was

created in 1995 by the Legislature to maintain the first all-payer claims data base (APCD) in the United States. This database includes claim records from most medical treatments that are provided to Maine citizens and that are paid for by private and public insurers. The Maine Health Data Organization also collects inpatient and outpatient encounter information on all episodes of care provided by Maine's hospitals and ambulatory surgical centers, as well as summary level financial and quality information provided by Maine hospitals. These data, termed *administrative* as opposed to *clinical* data, have proven immensely useful in the analysis of provider and health system performance.

The data enable the examination of care patterns and costs in the State. Maine employers in particular, as funders of health care, have used this information to identify high cost providers, high cost conditions, and the effects of employer-based wellness interventions on the cost of health care for their employee population. One analysis of the cost of health care in Maine, done for the Dirigo Health Agency's Maine Quality Forum, illuminated the impact of avoidable complications of chronic illness on the total costs of care in Maine. That report has led to policies promoting the adoption of "best practices" among primary care providers in Maine. Other analyses have advanced understanding of the use of expensive hospital emergency room care by different groups; provided comparative data that have helped hospitals to advance value-based purchasing; and shown different patterns in Maine and two comparison states in service use and cost through a path breaking tri-state variation study.

The demand for these data from business, government, insurers, health care providers, and health analysts, has been high and will only increase in the future. It is fair to say that the MHDO struggled to meet these demands on a timely and convenient basis in the past. There were reliability and timeliness issues with the availability of both claims data (particularly those from Medicare and Medicaid) and hospital inpatient and outpatient data. As a result, in 2011, proposed legislation (LD 1467) was originally submitted to completely revamp the

MHDO operations. The bill was modified and led to Resolve Chapter 109 (2011), which called for the establishment of a Work Group led by the Department of Health and Human Services to evaluate and report on options to “improve the availability and access to health care data.”

The Resolve identified four areas for evaluation:

1. Review the current structures of, and relationships among, the Maine Health Data Organization, the Maine Health Data Processing Center and Onpoint Health Data in order to evaluate the timeliness and effectiveness of the data received;
2. Review the current purposes and uses of the data, and limitations on access to the data, and considering additional uses for the data and changes that might be necessary to achieve and facilitate additional uses;
3. Consider federal and state privacy and security laws regarding the use and release of protected health information, including policy and technical changes needed to allow increased access to protected health information, and the feasibility of those changes; and
4. Consider the availability of the data, the most appropriate sources of the data, and the cost of providing the data.

Resolve Chapter 109 was later amended (LD 1818) to provide the Work Group additional time to complete its work. (See [Appendix A](#) for the Resolve; a complete record of committee meetings and documents is available at http://www.maine.gov/hit/ld_1818/index.html).

The Work Group convened in April 2012 and met at least monthly through the remainder of the year. The Group was led by elected Co-Chairs Dr. Josh Cutler and Colin McHugh. The Group accepted the working principle that health system reform and improvement depends upon the ability to objectively analyze the system’s performance in terms of cost and quality. Such analysis relies, in turn, on the maintenance of accurate and timely administrative and clinical health data that is accessible (with strict safeguards and confidentiality requirements) to patients, providers, purchasers, payers, and researchers.

The Work Group recognized that the path to the desired state requires broad consumer and stakeholder participation, and therefore issued a “Voice of the Customer” (VOC) survey in late spring. The VOC process led to several presentations and thoughtful discussions between the Work Group and experts in the health care data and claims field, including health services researchers, hospital and health system representatives, physicians, payers, public agencies, individual consumers, and employers.

What the Work Group heard above all else is that stakeholders are eager to gain access to timely and accurate health care data, including claims and clinical data, in order to move forward from the current state of our health care system towards meeting the goals of the Triple Aim (improving the individual experience of care; improving the health of populations; and reducing the per capita costs of care for populations).



The Triple Aim recognizes the necessity to *move away from paying providers for the volume* of services provided and to *migrate towards paying for value and quality* outcomes. At the core of this payment reform initiative is patient-centered health care and provider accountability. The model requires providers to assume greater accountability for the cost and quality of services provided, and rewards improved health outcomes and efficiencies. Payers and providers need to have health care data to monitor performance and make educated decisions to strive toward meeting the goals of the Triple Aim.

III. Voice of the Customer (VOC)

Although the LD 1818 Work Group represented a variety of interests, the Group believed that it was important to have input from additional stakeholders. As mentioned above, the Group issued an electronic survey in late spring to 140 groups and individuals, requesting that stakeholders answer three questions keeping in mind the four issues from the Resolve:

1. Which Needs and Expectations are being met by existing processes, relationships, and structures as it relates to the use of health care data?
2. Which Needs and Expectations are NOT being met by existing processes, relationships, and structures as it relates to the use of health care data?
3. What are the desired future uses of clinical and/or administrative claims data that are being considered?

See Appendix B for a summary of the 90+ VOC comments. The complete record, including presentations and papers submitted as part of the process, can be seen at http://www.maine.gov/hit/ld_1818/index.html.

Four major themes emerged from the results of the survey. The Group formed subcommittees, chaired by Work Group members, to address the four themes:

- Theme 1: Establish multi-stakeholder directed Data Governance Structures that optimize the collection, processing, and distribution (accessibility) of health care data.
(Dr. Josh Cutler, Chair)

- Theme 2: Implement technically-sound and scalable Data Processing Structures and Protocols that permit the timely, accurate, and cost effective submission and dissemination of pertinent health care data (both administrative and clinical). (Karynlee Harrington, Chair)
- Theme 3: Balance Consumer Privacy considerations regarding the safeguarding and disclosure of Protected Health Information (PHI) with the societal imperative to drive higher quality and more affordable health care. (Colin McHugh and Dawn Gallagher, Co-Chairs)
- Theme 4: Establish mechanisms to ensure that multi-stakeholder (including consumer) engagement and feedback is solicited and prioritized to ensure value is being derived from health care data. (Christine Torraca, Chair)

Subcommittees were asked to identify barriers to achieving each thematic goal, as well as the opportunities and their anticipated benefits. Recommendations were developed by each subcommittee and fed up to the full Work Group. Full subcommittee minutes and documents are available on line at http://www.maine.gov/hit/ld_1818/index.html.

The recommendations of the individual subcommittees are not consensus statements of the full Work Group. The recommendations did, however, help to inform Work Group discussions.

IV. The Resolve - Four Evaluation Areas and Summary Findings

After the work of the subcommittees concluded, the full Work Group held discussions and formulated responses to the four questions raised in the Resolve:

1. Review the current structures of and relationships among the Maine Health Data Organization, the Maine Health Data Processing Center and Onpoint Health Data in order to evaluate the timeliness and effectiveness of the data received;

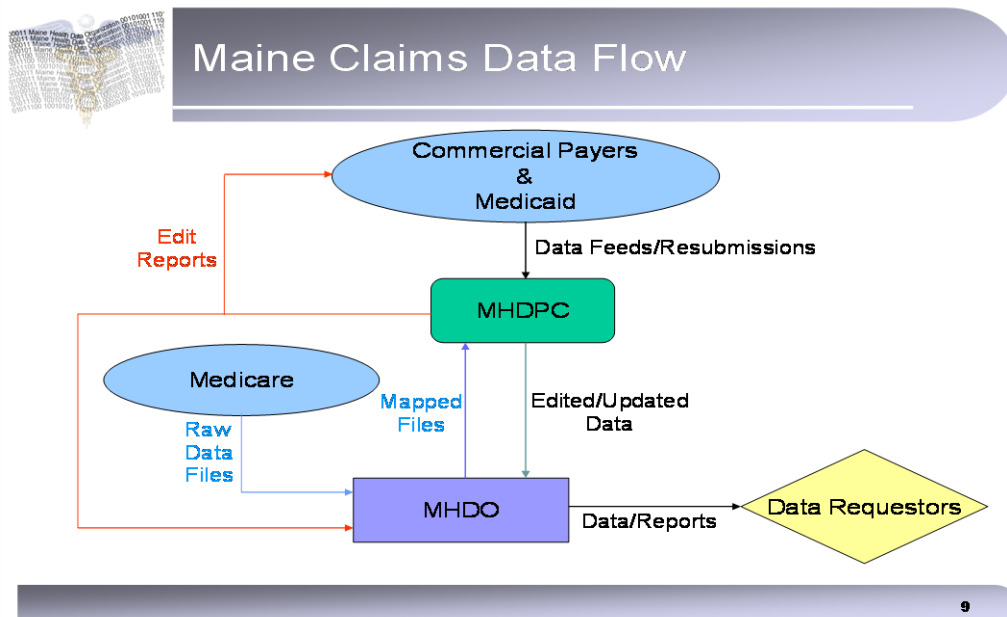
The Maine Health Data Organization (MHDO) maintains administrative, financial, and some limited clinical health data for use in policy development; adopts rules governing data collection, public access, and sanctions for failure to comply; sets fee schedules and assessments on health care facilities, payers, and third party administrators; and responds to requests for data. The MHDO furnishes reports on quality of care and price comparisons which are publicly accessible on the MHDO website. The MHDO also maintains the following databases:

- Hospital inpatient
- Hospital outpatient
- Hospital emergency department
- Non-hospital ambulatory services (1990 – 2004)
- Hospital financial
- Hospital organizational
- Quality data

Question No. 1 was raised to address concerns identified in 2009 and 2010. By the time the Work Group was formed in early 2011, the MHDO Board had already initiated plans and actions

to improve organizational effectiveness, produce timely and accurate data, achieve performance improvements, and restructure the MHDO board. Between December 2011 and December 2012, the MHDO brought its all-payer claims database (APCD) up to date, which includes data from the two public payers and commercial insurers. MHDO has developed a comprehensive plan to maintain its current level of performance into the future, which includes provisions for upgrading its technical infrastructure. This LD 1818 report will describe the past or “as-is” governance structure, and insight into the improvements made, or under consideration by, the MHDO Board.

The following diagram depicts the existing relationships of three key health data organizations: Maine Health Data Organization (MHDO), Onpoint (a nonprofit successor to the Maine Health Information Center), and the Maine Data Processing Center (“DPC” or “MHDPC”). It is important to note that the diagram reflects a structure that is being eliminated and replaced with a new more efficient model.



The MHDO and Onpoint were permitted by statute in 2001 to form a non-profit corporation, the Data Processing Center (DPC), in order to create a publicly available claims dataset.¹ The DPC has two funding sources: MHDO (60%) and Onpoint (40%). This funding supports the DPC’s efforts to collect medical, pharmaceutical, dental, and enrollment records from over 100 commercial payers and third party administrators (TPA). The Data Processing Center then aggregates these millions of records; implements of several layers of quality checks to ensure accuracy and quality; and creates a completed, “ready-to-go” dataset for the MHDO. This work is currently being done by Onpoint staff, under funding from the DPC. This arrangement provides an optimal data set for transmission to the MHDO, and provides technical liaison to both parties. DPC is governed by a board that consists of MHDO board members from various constituencies, including payers, providers, consumers, and employers; and MHDO and Onpoint administrators. The DPC Board oversees the organization’s activities related to data completeness, data quality, timeliness, and financial oversight. The table below outlines the roles and responsibilities of the MHDO and Onpoint.

Onpoint Health Data	MHDO
Payer communication, on-boarding	Rulemaking – data collection, release
Payer registration – initial, ongoing	Payer compliance
Secure upload and PHI encryption	Submitter role – Medicare (including mapping to APCD format), MaineCare
Data collection, validation in conformance with state regulations	Loading, warehousing data
Data specs, submission schema, reporting systems maintenance	Extracts to approved users
Master Person Index	Administrative – fee assessment to payers/providers, users; board support
Master Provider Index	
Extract preparation – qtrly to MHDO	

¹ The claims dataset is described in MHDO Rule Chapter 243:
[dhttp://www.maine.gov/sos/cec/rules/90/90/590/590c243.doc](http://www.maine.gov/sos/cec/rules/90/90/590/590c243.doc)

A detailed analysis of factors impacting all-payer claims data timeliness, as well as recommendations for improvement, was provided by Onpoint to the MHDO Board, and is included in this report as Appendix C.

While it is helpful to summarize the historical structure of health care data governance, it is important to talk in more detail about the transformation of the MHDO governance and structure. In late 2010, Deloitte, a private consulting firm, was hired to assess MHDO's current claims data processing efforts. The Deloitte report sought to address basic questions about the current workings of MHDO, and to identify the barriers to timely provision of claims data to stakeholders. The report also provided a set of recommendations for improvement on three components -- process, technology, and people.

The Deloitte report described an organization where most of the staff was focused on day-to-day maintenance and operations tasks. There were no fully articulated processes related to testing and quality assurance that would allow issues to be discovered and resolved in a timely manner. The data architecture was not tuned to provide the full range of capabilities to its users. Most of its leadership policies were ad hoc and not geared to support data processing and growth needs.

The report recommended that MHDO create a leadership structure with clear roles and responsibilities to improve its decision making processes. It advised MHDO to establish principles and guidelines for the creation of data models, along with metrics to measure performance and adherence to the models. The Report concluded that these recommendations would enable MHDO to better govern and support data management practices and policies. The complete Deloitte report can be read at the MHDO website at http://mndo.maine.gov/imhdo/_pdf/MHDO_Assessment%20Final%2012-05-2010.pdf.

Since the writing of the Deloitte report, and more recently since the Work Group initiated its evaluation efforts, the MHDO has embarked on a comprehensive plan to improve its

performance and better meet the needs of data requestors and submitters. The MHDO Board adopted a new strategic vision and a set of business imperatives to guide MHDO to the future state. The new strategic vision is stated below, followed by the six business imperatives, and the current status of the six imperatives.

The pillars of the new **vision** include:

- *Responsive and timely data*: clearly communicating to our clients what data are available and managing data release to published timeframes.
- *Accurate data*: ensuring consistency and conformity of claims submissions
- *Accessible data*: providing self-service applications where possible and removing barriers to data access.
- *Streamlined process*: building efficient processes for data gathering and release.
- *Secure data*: protecting the confidentiality of personal health data – electronic threats change and systems must adapt to meet these challenges

The six **business imperatives** are:

1. *Restructuring* to significantly reduce number of board members, while retaining stakeholder diversity and balance;
2. *Recommitting* to maintaining the agency's independent status;
3. *Refocusing* attention on improvements in the current data transformation process, using the State's RFP process to secure a new data contract;
4. *Enhancing* communication with partner agencies, stakeholders, and end users;
5. *Appointing* an interim executive director; and
6. *Initiating* a search for permanent executive director.

The MHDO Board is now implementing these business imperatives. The existing MHDO Board structure, created by State law in 1995, consists of 21 members from the public and private

sectors. Over the years, the Board's ability to function and move the MHDO forward was hampered by the large size of the Board. Over the past year, MHDO has informally reduced the size of the Board to help achieve their goal of having a nimble, responsive, and appropriately engaged board of directors. The LD 1818 Work Group supports a formal reconstitution of the MHDO Board, with increased emphasis on its public role. (See [Appendix D](#) for a summary of planned improvements that MHDO presented to the Work Group.)

In early summer 2012, the MHDO issued a request for proposal for a "highly robust and secure data warehouse" built on an architecture that can support:

- high volumes of multiple data files at rapid speeds;
- a set of common data structures available for third party use; and
- web access to data and reports.

MHDO envisions creating a shared utility that will provide value for multiple entities.

The MHDO has selected a vendor and, as of early February 2013, is negotiating final terms with that vendor. As recommended by the Deloitte Report, and affirmed by the MHDO Board, MHDO will execute an agreement that specifies the levels of security, performance, and operation expected of the vendor, as well as penalties for non-compliance with measurable performance targets.

MHDO will require that the vendor:

- Work collaboratively with MHDO to implement the Board's priorities;
- Convert the MHDO data into the new warehouse structure;
- Provide a "dashboard" view of the warehouse in real time to MHDO staff showing compliance, efficiency, load, and query information;
- Test processes to make changes to the system as needed; and

- Maintain documentation and tools to allow MHDO staff to operate the system.

As part of the reconstituted governance and data warehouse changes, the contract with the new vendor will be directly with MHDO. The Board of Directors of the non-profit Maine Health Data Processing Center (DPC) has agreed to dissolve itself in 2013.

The MHDO's latest release of claims data contains complete data sets from private payers and Medicaid through September 2012, and from Medicare through 2010 (which is the most current data available from the Federal government). It marks the first time that the most current Medicare and Medicaid data have *both* been available in the data set. This high-quality and complete data will prove extremely useful.

The MHDO members of the LD 1818 Work Group acknowledge that considerable work remains to be done. The Work Group is pleased with the work completed by the MHDO in the past year. The Work Group believes that the MHDO Board should be held accountable for delivering on the promise of its new vision and business imperatives through disciplined execution of its plans and robust stakeholder involvement. The Work Group recommends that the MHDO include in its annual reports to the Maine Legislature updates on its progress in achieving its vision and business imperatives, as well as furthering the goals of this report.

2. Review the current purposes and uses of the data and limitations on access to the data and considering additional uses for the data and changes that might be necessary to achieve and facilitate additional uses;

A. The Policy Case for Linking Claims and Clinical Data

Analysis of payments alone are not sufficient for a complete view of the value that the payers of health care – who are ultimately the wage earners and taxpayers of the state – are getting for their investment. Although claims analysis is useful for observing the *processes* of care, it is

not adequate for evaluating the *outcomes* of care. For this, clinical data in addition to administrative data are necessary. This section briefly reviews the classification and types of quality data to understand their use in health system performance analysis.

Quality measurement is concerned with three domains of measurement: structure, process, and outcome.

- Structural quality measures describe attributes of providers (hospital bed size, number of primary care physicians in a geographic area).
- Process measures describe the components of an encounter between a provider and a patient (tests ordered, medication prescribed).
- Outcome measures describe the effect of care on aspects of patient (or population) well-being, such as survival, return to function, or state of control of a chronic illness.

Administrative data, such as claims data, can provide insights into payments, utilization, and care processes. They are valuable to the extent that adherence to certain processes (timely intervention for heart attack treatment, for example) is associated with improved outcomes (lower mortality rate in heart attack patients). However, outcomes data, which is arguably the most useful quality information, is not available in administrative data sets. The MHDO and the Maine Quality Forum have collected some clinical process and outcome measures from hospitals for several years, as have other public and private entities, including the federal Centers for Medicare and Medicaid Services (CMS) and Leapfrog (a national employer coalition concerned about healthcare safety). These data have described hospital performance on healthcare-associated infection and other aspects of patient safety. The data have shown a relationship between adherence to recommended “best practice” care processes and better outcomes. Reporting on these processes and related outcomes has been done on a hospital level; processes (derived from administrative and clinical data bases) and outcomes for populations of individual patients (derived from clinical data bases and registries) have not

been linked. When Maine’s all-payer claims database (APCD) was organized, there were no good ways to collect large amounts of clinical outcomes data for populations. Now, however, with the development of electronic health records and clinical outcomes registries, it is feasible to describe health outcomes in large populations of patients.

There is considerable evidence and expert opinion that the marriage of cost data with outcomes data makes robust analysis of the overall performance of health care providers and of the value of health care in Maine possible. Dr. John E. Wennberg, a noted health services researcher and founder of the Dartmouth Atlas of Health Care, which catalogs variations in care processes in the United States using Medicare claims analysis, wrote *“Claims data need to be augmented by critical information extracted from patient records and obtained directly from patients.”*²

The limitations of claims data alone to evaluate provider quality was demonstrated in a study showing that hospital performance on process measures reported by Medicare in its consumer-facing Hospital Compare website were only modestly correlated with outcomes (mortality rates).³ In a Brookings Institution review of the role of clinical data registries in care improvement, the following statement was made: *“Registries can play an important role in better health care performance measurement. To achieve this, clinical data from registries must be integrated with claims data to create a hybrid database that can be used to improve care and, in turn, calculate more valid and comprehensive measures of the quality and cost of medical care.”*⁴

Michael Porter of the Harvard Business School, who has written extensively on value in health care, states, *“The only way to accurately measure value... is to track patient outcomes and costs*

² Wennberg JE, Fisher ES, Skinner JS. Geography and the Debate over Medicare Reform. Health Affairs 2002; W96 – W114.

³ Werner RM, Bradlow ET. Relationship Between Medicare’s Hospital Compare Performance Measures and Mortality Rates. JAMA 2006; 296 (22): 2694 – 2702.

longitudinally.”⁵ Similarly, in a critique of Great Britain’s National Health Service approach to measuring quality, Mountford and Davie found that quality reports have had:

*[a] focus on process and proxies, not on outcomes that matter to patients. To date, the dominant focus of quality measurement and reporting has been on processes and inputs to care, not on patient-relevant outcomes. Process measures can have advantages. For example, they are often easier to measure than outcomes, they require less risk adjustment, and there are many examples in which a favorable patient outcome has resulted despite a defective process (or in which an unfavorable outcome has followed a faultless process). However, undue focus on process and proxy measures can have serious and often surprising consequences. Patients may have worse outcomes as a result. For example, higher mortality in high-risk patients with type 2 diabetes was associated with aggressive intervention to achieve normal glycosylated hemoglobin levels.*⁶

A large body of evidence now supports the limitation of administrative data alone to describe or even drive improvement in health care.⁷

B. The Current State of Claims and Clinical Governance

Having reviewed the classifications and types of quality data, we now turn to the current state of governance structures for claims and clinical data:

- Claims data are kept in the all-payer claims database (APCD) managed by the MHDO, an independent State agency governed by a board of directors, representing both public agencies and private entities. MHDO has the authority to require hospitals and payers to submit claims and quality data. By statute, MHDO also has authority to compel

⁴ How Registries Can Help Performance Data Improve Care. Engelberg Center for Health Care Reform at Brookings, 2010, Accessed at <http://www.rwjf.org/content/dam/farm/reports/reports/2010/rwjf61984>.

⁵ Porter ME. What is Value in Health Care. N Engl J Med 2010; 363:2477 – 2481.

⁶ Mountford J, Davie C. Toward an Outcomes-based Health Care System. JAMA 2010; 304,(21): 2407-2408.

⁷ See Hammill BG et al. Incremental Value of Claims Data beyond Clinical Data in Predicting 30-day Outcomes after Heart Failure Hospitalization. Circ Cardiovasc Qual Outcomes, 2011 Jan 1;4(1):60-7. See also Farmer SA, et al. Tension Between Quality Measurement, Public Quality Reporting, and Pay for Performance. JAMA 2013; 309(4):349-350)

submission of clinical data from providers, and there are precedents for collecting and housing data at MHDO.

- Clinical data is held in several repositories. It is owned by, and its use controlled by, the providers who generate it. “Real-time” hospital and provider clinical data are often submitted to what is called a “Health Information Exchange” (HIE). In Maine many hospitals and providers participate in an HIE through customer agreements with HealthInfoNet, a non-profit company, governed by a board of directors, that operates a state-wide Health Information Exchange. Participation in the HIE is voluntary. Its current framework does not provide a mechanism to require providers to submit clinical data, or for Health InfoNet to release clinical data, unless permitted under its customer agreements. Over the past year, HealthInfoNet has been working with its data submitters, stakeholder committees and board of directors to develop the company’s policy on clinical data use, data release, and responses to requests for data. Health InfoNet (HIN) is considering using the framework that the MHDO uses to decide data requests (such as the purpose of the request), with decision making authority for releasing clinical data from the HIE to reside with the HIN board of directors. HIN anticipates that these policies will be finalized in the spring of 2013.

Electronic health records (EHR) carry with them the potential for reporting massive amounts of clinical data, much of which is in the category of outcomes. Population disease registries maintained by providers and health information exchanges (HIE) such as Maine’s HealthInfoNet have demonstrated the potential of EHR to assemble and analyze clinical information from large populations for the purposes of quality analysis and care improvement. A next logical step in creating the toolset necessary for development of a *learning health system* for Maine is building the capability of linking these clinical data with administrative data already in place in the MHDO.

Considerable pressure already exists for providers to engage in care improvement initiatives, supported by the monitoring and analysis of cost and quality data. The Maine State Employees Health Commission has been an innovator in the development of incentives for its members to choose higher value providers. Medicare, through its Shared Savings, Bundled Payment, and medical home programs, has offered providers the opportunity to share in the savings generated by providing high quality care at a lower cost. MaineCare has established a Patient-Centered Medical Home Pilot and is also developing a Value-Based Purchasing program. The Maine Health Management Coalition Foundation, a public charity, has developed and shared robust health care cost and quality information, and provided it not only to its members, but to the public free of charge. This data has had a major impact on improving health care quality and safety in Maine.

Improvement in the availability of administrative data, broadening the range of clinical quality measures, and developing safe and reliable rules governing the linkage of these two types of health data would allow the assessment of both quality and cost by all Maine stakeholders. This will set the stage for providers to continuously improve, for consumers to make better informed decisions, and for payers to derive value from Maine's health care system.

The value of integrated claims and clinical data was recognized and emphasized by several respondents to the "VOC" survey. Select survey responses include:

"Data needs to be aggressively used by all appropriate parties to improve the delivery of health care, and therefore made available by a public entity with appropriate governance and safeguards to as many qualified users as possible who will work to improve the health and safety of Maine people."

"A common, shared data source of integrated clinical and claims data for all parties to use – with appropriate privacy, security and legal safeguards and role-based access – will serve as the foundation to system and payment reform. All approved users should have fair, affordable and equitable access to the data for the purposes of care improvement."

Although there was consensus on the value of linking the claims and clinical data, the challenge for the Work Group was establishing processes and mechanisms that should be used to accomplish the linking.

Throughout the course of stakeholder discussions there was a recurring theme regarding the importance of providers and consumers having equal access to data. One VOC respondent said, *"A publicly governed and accountable entity should maintain the functions of the MHDO. Public governance provides the greatest accountability and protection for data users and could provide fair and equal data access to all users."* Another VOC respondent stated, *"The age of competing for market share by controlling access to data is over. Transparent all-payer data should be made widely available and competition should be based solely on performance."*

The issue of having access to health data must be balanced with privacy issues. As one VOC respondent pointed out, *"While there may be value to expanding uses of the MHDO database or to linkage with other databases, these decisions should be made with patient's rights at the fore."* Another respondent stated, *"There are lots of questions about crossing the line between de- and identifiable data. We [health systems] want to maintain control of clinical PHI. Careful assessment of what provider organizations are compelled to do vs. doing it voluntarily [is necessary]."*⁸

Surmising that neither the market nor the government can provide the perfect solution, it is suggested that the combined effort of both public and private resources continue. In fact, MHDO has contracted with HealthInfoNet to test the feasibility and costs of linking administrative and clinical information. This pilot should inform next steps concerning the technical requirements, cost details, and optimal governance of these potential new capabilities.

⁸ Brackets added to complete the respondent's thought.

C. Improve and Facilitate Health Data Uses—Maine Quality Forum

Question 2 also asks the Group to examine current health data uses and to look at ways to facilitate improved and expanded uses.

Although the MHDO collects a wide array of health care data and has general responsibility for its provision, analytical work on the data is conducted in collaboration with State agencies. For example, Maine's Center for Disease Control and Prevention (CDC) and MaineCare, each within the Department of Health and Human Services, perform analytic services unique to their authority.

Recognizing the need for population health analytics, in 2003 Maine established the Maine Quality Forum (MQF) as a function under the Dirigo Health Agency. The MQF's primary purposes, assigned in the enabling legislation, include:

- Research dissemination on quality, evidence-based medicine, and patient safety to promote best practices which MHDO must use as the basis of MHDO rules;
- Coordinate with the MHDO the collection of health care quality data in the State, to minimize duplication and burden on the providers of data;
- Work collaboratively with the MHDO and providers to report in useable formats health care quality information to consumers, purchasers, providers, insurers and policy makers;
- Make available information on quality of services on a publicly accessible website and conduct education campaigns;
- Conduct technology assessment reviews to guide the use and distribution of new technologies; and
- Promote the adoption of electronic health information technology.

Together, MHDO and MQF have developed a data base of clinical measures, including outcome and process measures, that has advanced the public's understanding of care quality in Maine's hospitals. These measures include process and outcome indicators in areas such as heart disease, pneumonia, and healthcare-associated infection.

The MQF has analyzed and reported on health care variation in utilization, quality, and cost, using data from MHDO data bases. It has published an annual report on the incidence (and efforts at control) of health care-associated infections since 2008, using MHDO quality data; commissioned and supervised a study of health care cost drivers in Maine in 2009, using the all payer claims data; and reports on its website on variations in care patterns among Maine's healthcare service areas, using hospital discharge data – see the MQF website at <http://www.mainequalityforum.gov/>. These and other MQF projects have informed health policy development in State government and in the private sector.

The Maine Quality Forum is a function of the Dirigo Health Agency and governed by the Dirigo Board of Directors. The current funding mechanism for the Dirigo Agency will cease at the end of 2013. The Dirigo Board of Directors anticipates and supports funding the operations of the MQF through State Fiscal Year 2015 with existing reserves. (That proposal is in the current budget process in the Legislature.)

The Work Group believes that now is the opportunity to continue the work of the MQF in a manner that preserves this important and unduplicated capability within State government. The functions that the MQF currently perform, especially those done in collaboration with MHDO, will still be needed in the future. The Group believes that the MQF could be relocated within the MHDO (conditioned on funding availability, administrative efficiencies, and staffing needs). In addition to sustaining the ability of the MHDO to perform data analysis on its administrative and quality data sets, incorporating MQF would provide guidance to MHDO on

choices of indicators collected under MHDO Chapter 270, *Uniform Reporting System for Quality Data Sets*; on the development of reports for the public and consumers regarding health care providers; and on the use of linked clinical and administrative data for these reports. The MQF Advisory Council has provided, and could continue to provide, a portal for public input into this guidance.

D. Active Multi-Stakeholder Engagement

One of the four themes emerging from the VOC survey was the need to establish mechanisms to ensure that multi-stakeholder engagement and feedback is solicited and prioritized, to ensure that value is being derived from health care data. The subcommittee charged with addressing this theme made three recommendations to improve on the current state:

- Clarify the role of government, relative to non-governmental entities, of the respective contributions to the creation of health care data bases and reporting;
- Build on current mechanisms that engage stakeholder groups to gather input and feedback, discuss opportunities for engagement and education, and continuously improve the current state; and
- Establish a process of accountability and transparency for the stakeholder input system aligned with the data governance structure, with the ultimate goal being multi-stakeholder collaboration to ensure the greatest value is derived from this work.

The subcommittee concluded that, in order to promote efficiency and meaningful outcomes for stakeholders, there needed to be ongoing mechanisms to report activities and coordinate efforts. These mechanisms should include articulated goals against which its effectiveness can be evaluated on a regular basis (see Appendix E for an inventory of engagement mechanisms, as well as notes on sources of the information provided on the next page).

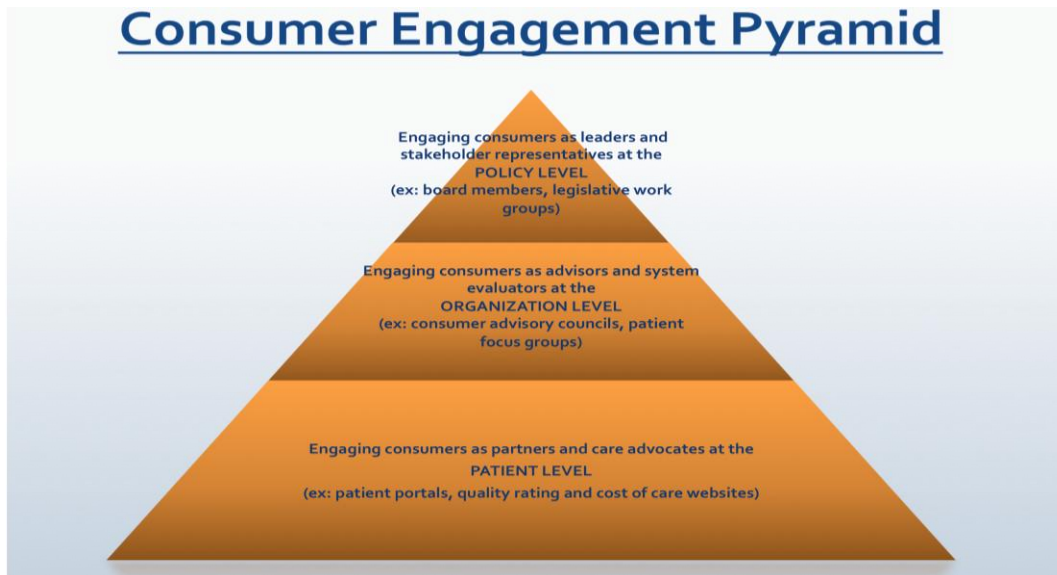
Regarding consumers in particular, the establishment of mechanisms to ensure consumer – patient engagement has been recognized nationally as instrumental to meeting the goals of the Triple Aim. The Commonwealth Fund calls consumer engagement “a core driver toward a high performance health system.” The value of engaging consumer stakeholders was reinforced by one VOC respondent, who succinctly stated,

“Data users - including consumers - should have input into the structure, design, and purpose of the state’s data systems to maximize its use for and by all stakeholders, including the public.”

Another provided a compelling rationale for consumer engagement;

“Without this transparency patients cannot truly be engaged or empowered - because we lack available data and information, and with the odds as high as 1 in 3 of experiencing medical harm in a hospital⁹, healthcare consumers are choosing blindly every day..

To support consumer engagement and provide a framework that can change and adapt as the health Information field evolves, a consumer engagement pyramid which illustrates the three levels of engagement--patient, organization and policy—was developed by one of our Task Members, Poppy Arford, and several of her colleagues:



3. Consider federal and state privacy and security laws regarding the use and release of protected health information, including policy and technical changes needed to allow increased access to protected health information and the feasibility of those changes;

Protected health information (PHI) is defined under federal law as any information about health status, provision of health care, or payment for health care that can be linked to a specific individual. The federal HIPAA (Health Insurance Portability and Accountability Act) law identifies 18 elements (including name, telephone number, email address, social security number, and unique identifying number such as a medical record number) that are considered as elements of PHI.

The federal HIPAA law limits the disclosure of identifiable health information to treatment, payment and operations of the health care practice, and a few other specific purposes. There are more restrictive federal laws governing personal health information related to substance abuse. The general rule is that, unless allowed under these laws, disclosure is not permitted. Clinical data bases, such as the health information exchange operated by HealthInfoNet; claims and quality data bases, such as those operated by MHDO; and payer and other data bases, contain some protected health information (PHI). Regardless of where the data resides, utmost care for privacy and security must be maintained.

Considerable VOC feedback was provided by various stakeholders as it relates to the broadening of access to healthcare data, including the following competing comments:

“While there may be value to expanding uses of the MHDO database or to linkage with other databases, these decisions should be made with patient’s rights at the fore. Often those doing the hard work of providing us with healthcare get so excited about increasing efficiency or improving coordination of care that patient notice, privacy and consent can get lost.”

⁹ See <http://www.ama-assn.org/amednews/2011/04/18/prl20418.htm>

“As patient advocates and defenders of personal privacy, we urge continual focus and commitment to privacy, confidentiality and security. Patient rights must be the highest priority in Maine’s electronic health information system, and we hope the State will continue to demonstrate meaningful commitments to patient privacy.”

“Patient identified data must be included but identifiable only at the patient/provider level to allow providers to effectively improve care for their patients. Identified data enables the combining of different data sources to allow a meaningful and longitudinal understanding of utilization, care patterns, and outcomes.”

“Health care providers need data with personal health information in a HIPAA compliant way so they can use it to improve care for those patients they are treating. Right now we have providers willing to take responsibility for the quality and cost of their patients and they don’t have good data readily available. I hear words like ‘betrayal’ and ‘tying our hands behind our backs’ from providers.”

To better understand the nature of protected health information law, the Work Group asked the Legal Work Group (attorneys and health information privacy experts who are periodically convened by the Office of the State Coordinator Health Information Technology Steering Committee) to provide information and guidance on this issue.

As background, the Legal Work Group presented to the Work Group a thorough analysis of federal and State laws pertaining to HIPAA, Substance Abuse and Alcohol Abuse, Mental Health, HIV and how the MHDO, HealthInfoNet and the Health Information Exchange are affected by the laws. A graph depicting these laws is shown below:

	General PHI (non-sensitive)	PHI Mental Health	PHI Federal Substance Abuse Program	PHI HIV
Informed Consent	Disclosure Allowed	Disclosure Allowed	Disclosure Allowed	Disclosure Allowed
Treatment Payment Operations	Allowed for TPO	Allowed for payment; T+O are restricted + vary for agency vs. clinician	Only with patient consent	Allowed for direct treatment
Public Health	Allowed when required by law	Restricted; can disclose to DHHS in limited circumstances	No exception listed; LWG opinion patient consent required	Allowed when required by law
Fund Raising	Allowed for entity	Consent required	No exception listed; LWG opinion patient consent required	Statute is silent; LWG opinion use requires consent
Research	Restricted	Restricted; limited exceptions	Restricted	Restricted; researchers can't re-disclose
Marketing	Consent required	Consent required	Consent required	Consent required

A full copy of the LWG report and supporting documents is contained in Appendices F and G.¹⁰

Unless otherwise permitted by federal law, State laws cannot contradict federal laws and rules. The federal Substance Abuse laws are very inflexible and would require considerable efforts at the federal level to make changes to the laws. HIPAA, even though it is a federal law, allows states some flexibility in how they enforce certain elements. The Legislature has the ability to amend Maine laws on access to protected health information. The MHDO has the authority under Maine law to modify its rules (subject to the Administrative Procedures Act).

¹⁰ Many LWG members stated that they viewed the scope of the LWG as providing a factual review of the current federal and state laws and rules governing protected health information (PHI). In that respect, the LWG did not make what might be termed “subjective” recommendations. Rather, the LWG provided an analysis that was factual in nature.

The Resolve asked the Work Group to consider changes needed to “increase access” to protected health information. The Work Group viewed this question in two different contexts: *improving* access to PHI and *increasing* access to PHI.

Subject to the federal and State laws described above, existing laws allow payers, Accountable Care Organizations, hospital systems and their health care providers, and health care practices to have access to, and to exchange/release their patients’ records including protected health information. However, MHDO is precluded by Maine law from releasing PHI. Currently, encrypted data is fed from payers, including Medicare and Medicaid (MaineCare), to the DPC which then forwards the encrypted data to the MHDO claims and quality data bases. MHDO provides aggregated claims and quality data reports. These reports are useful to identify costs and quality at a high level, such as the total number of claims that had a certain diagnostic code, such as hypertension, but do not report claims and quality data that could help improve individual patient outcomes. Although providers and hospitals could benefit from receiving claims and quality data available in the MHDO data bases, the MHDO cannot release protected health information, even to providers who have a direct relationship with the patient. A way to *improve* access to PHI is to allow the MHDO to have the same legal rights and responsibilities to exchange/release PHI as federal and State laws allow for other entities. This may be accomplished by the Legislature amending the MHDO statute to allow MHDO to modify its existing rule to improve access to PHI for purposes allowed under HIPAA and other federal and State laws. The existing applicable MHDO statute and rules are found in Appendices H and I.

As evidenced by the selected VOC comments above, increasing access to personal health information for purposes other than what are currently thought of as “treatment, payment and operations of the practice” requires further policy discussions. There could be legitimate and appropriate reasons, including public policy considerations, for increasing access to PHI. The Work Group is not putting forth specific changes to Maine law, yet we do believe that the

comprehensive review completed by the LWG will certainly guide future directions relating to increasing access to personal health information.

4. Consider the availability of the data, the most appropriate sources of the data and the cost of providing the data.

Question No. 4 was not discussed in detail, as the Group did not have sufficient time to gather and analyze all of the sources of data and the costs of providing the data at the level necessary to make an informed presentation.

Given the relative small size of Maine, competing data and reporting structures may pose undue costs to system stakeholders and unnecessary fragmentation of the overall system. As one VOC respondent stated, *“Resources should be used effectively and care should be taken to avoid unnecessary duplication of data systems and the resources needed to support them. Data is a resource that is only valuable when it is accessible and used effectively.”*

Avoiding fragmentation and duplication of effort, and not paying twice (or more) for the same data is critical because whether the submitting or receiving entities are public or private, they all face funding challenges. To that end, the Work Group supports an examination of data sets that are currently reported to the various entities to determine whether the data are needed; the value of the data; whether the data submissions are efficient and avoid duplication; the cost of providing the data; and an analysis of funding sources. The Work Group believes that the following statement should guide efforts to address these issues:

Maine needs to think strategically about the data we really need compared to the data we now collect and the costs of collecting that data; sustainable financial business models that are efficient and avoid fragmentation and duplication while providing the best value for the data; and how to best use the data to improve quality and health outcomes.

V. Next Steps

When the full Work Group reconvened to discuss the four sets of subcommittee recommendations, there was not consensus that the LD 1818 Report should contain specific recommendations for legislation. The Group believes that we need to move forward and that path requires both short and long term steps. Some steps should be taken in 2013 to set improvements in motion while knowledgeable stakeholders further examine and refine actions based on emerging technology and policy developments. This course ensures that we take actions that are needed today, while recognizing that health care data needs and technology will continually evolve.

The following steps are already underway or under serious consideration in existing organizations. The Work Group wishes to express its support for:

- 1) Continuing the work underway by the MHDO Board to implement its new vision and business imperatives by a Board that is held publically accountable for a disciplined execution of its plans with robust stakeholder involvement. Over the past two years, the MHDO Board has informally transformed itself into a smaller, more responsive and accountable board. The joint Committee for Health and Human Services has the authority under Resolve, Chapter 109 (2011) to report out legislation amending the MHDO statute (created in 1995) to reflect this transformation to a modern-day Board structure that will meet the future needs of the State's health care data organization. The Work Group understands that the MHDO board is preparing a legislative proposal to significantly reduce the size of the MHDO Board in order to be more nimble and effective, while still

maintaining representation of a broad group of stakeholders including employers, providers, insurance plans, state agencies and consumers.

- 2) Studying viable financial models, protocols, data management, privacy, and encryption policies by the reconstituted MHDO Board in 2013. This will lead to improved efficiency for current data submitters, and to standards for the use of linked databases (in which MHDO is involved).
- 3) Determining the feasibility of linking administrative claims and clinical data at an affordable cost through the close monitoring of the current terms of the contract between MHDO and HealthInfoNet. The monitoring should be conducted by a group of knowledgeable stakeholders who understand the myriad of issues posed in this report. The MHDO should report back to the Legislature on the results of this pilot.
- 4) Conducting a collaborative strategic examination on the health care data we really need compared to the data we now collect, and of the costs of collecting that data; identifying sustainable financial business models that are efficient, avoid fragmentation and duplication, and provide the best value for data; and identifying the best ways to use the data to improve quality and health outcomes.
- 5) Leveraging federal dollars to promote the use of electronic health records, access to health care data, and the development of reporting systems which move toward achieving the Triple Aim. This can be done through a collaborative effort between MHDO and Maine's Office of the State Coordinator for HIT to

leverage public funding under sources such as the federal Health Information Technology Act and the Medicaid Meaningful Use Program.

- 6) Continuing the positions the Maine Quality Forum (MQF) within MHDO in order to support ongoing data projects focused on quality improvement across the Maine health care delivery system; maximizing the public use of existing and future data assets of the MHDO; and providing an opportunity for multi-stakeholder engagement. This recommendation is conditioned on the availability of funding, and on an analysis of administrative efficiencies and staffing needs.

After the completion of these “next step” items, further legislation may need to be considered to more fully inform ensuing policy discussions, modify existing laws, as well as implement new laws and rules.

Comments from individual committee members on earlier drafts of this report are included in Appendix J.

VI. Conclusion

The experience of our Work Group has illustrated the importance of health data in Maine, and the passion and interest that its collection and use evoke among wide audiences in Maine. We wish to acknowledge and thank all of the groups and individuals who have contributed their ideas and time to this effort.

Maine has been in the forefront of the country in its health data collection and use. But the field is changing, as new technologies and practices enabling the linking of claims and clinical data become more widespread and practical. Maine needs to keep its leadership position, and to reap the benefits in terms of better and more affordable health care. This is an issue that justifies continued public attention in the coming years.

Appendix A: Resolve Establishing Work Group

RESOLVE Chapter 109, LD 1467, 125th Maine State Legislature

Resolve, To Evaluate the All-payor Claims Database System for the State
HP1076, on - First Regular Session - 125th Maine Legislature

Sec. 1 Creation of working group. Resolved: That the Department of Health and Human Services, referred to in this resolve as "the department," shall establish and convene a working group to evaluate options and actions available to improve the availability of and access to health care data and to examine the all-payor claims database system in the State; and be it further

Sec. 2 Membership. Resolved: That the Commissioner of Health and Human Services shall invite 17 persons to participate in the working group, as follows:

1. Two representatives of health insurance carriers;
2. Two representatives of health care providers, one member representing hospitals and one member
3. Two representatives of employers, one member representing a statewide health management representing physicians; coalition and one member representing a statewide chamber of commerce;
4. One representative of consumers;
5. One expert in both state and federal privacy laws;
6. One representative of the Maine Health Data Organization;
7. One representative of the Maine Health Data Processing Center;
8. One representative of Onpoint Health Data;
9. One representative of the Department of Administrative and Financial Services, Office of Information Technology
10. One representative of HealthInfoNet;
11. One representative of the MaineCare program within the department;
12. One representative of the federal Medicare program;
13. One representative of the Office of the Attorney General; and
14. One representative of the Maine Quality Forum; and be it further

Sec. 3 Cochairs. Resolved: That the members of the working group shall select 2 of the members to serve as cochairs; and be it further

Sec. 4 Evaluation. Resolved: That the working group shall consider changes to the State's allpayor claims database system to improve the availability of and access to health care data by:

1. Reviewing the current structures of and relationships among the Maine Health Data Organization, the Maine Health Data Processing Center and Onpoint Health Data in order to evaluate the timeliness and effectiveness of the data received; RESOLVE Chapter 109, LD 1467, 125th Maine State Legislature Resolve, To Evaluate the All-payor Claims Database System for the State HP1076, on - First Regular Session - 125th Maine Legislature, page 2
2. Reviewing the current purposes and uses of the data and limitations on access to the data and considering additional uses for the data and changes that might be necessary to achieve and facilitate additional uses;
3. Considering federal and state privacy and security laws regarding the use and release of protected health information, including policy and technical changes needed to allow increased access to protected health information and the feasibility of those changes; and
4. Considering the availability of the data, the most appropriate sources of the data and the cost of providing the data; and be it further

Sec. 5 Funding and staffing. Resolved: That the department shall provide staffing assistance to the working group through contracted professional services and shall seek outside nonstate funding to support staffing services and administrative costs for the working group. If adequate funding is not obtained, the working group may not convene or incur any expenses; and be it further

Sec. 6 Report. Resolved: That, by January 31, 2012, the department shall report the recommendations based on the findings and conclusions, determined by vote, of the working group, along with any recommended implementing legislation, to the Joint Standing Committee on Health and Human Services.

Appendix B: Themes from Voice of the Customer Exercise

Theme 1: Establishing multi-stakeholder directed Data Governance Structures that optimize the collection, processing, and distribution (accessibility) of health care data.

- Resources should be used effectively and care should be taken to avoid unnecessary duplication of data systems and the resources needed to support them. Data is a resource that is only valuable when it is accessible and used effectively.
- Management of the APCD and other data sets by state government through the independent agency structure and governed by a multi-stakeholder board.
- A publicly governed and accountable entity should maintain the functions of the MHDO. Public governance provides the greatest accountability and protection for data users and could provide fair and equal data access to all users.
- Data users- including consumers- should have input into the structure, design, and purpose of the state's data systems to maximize its use for and by all stakeholders, including the public.
- A common, shared data source of integrated clinical and claims data for all parties to use – with appropriate privacy, security and legal safeguards and role-based access – will serve as the foundation to system and payment reform. All approved users should have fair, affordable and equitable access to the data for the purposes of care improvement.
- The focus should be on developing a combined data warehouse to which appropriate entities have access for approved purposes to improve the health of Maine people
- Data needs to be aggressively used by all appropriate parties to improve the delivery of health care, and therefore made available by a public entity with appropriate governance and safeguards to as many qualified users as possible who will work to improve the health and safety of Maine people.
- There is still no “all payer” database available. We need commercial, Medicaid, and Medicare claims data combined in a usable data warehouse
- Integrated clinical data, claims, health risk, and outcomes data is the optimal source of information for care improvement and high value.
- Information created from healthcare data should be made transparent and publically available in aggregate with the appropriate safeguards, processes, and criteria for reliability.
- Lots of questions about crossing the line between de- and id-data. We want to maintain control of clinical PHI. Careful assessment of what provider organizations are compelled vs. doing it voluntary.
- In theory, we would be interested in seeing the full MHDO data. When we get data from CMS, we get patient identifiable information. One thing that would need to be

considered is the ability to get identifiable data from public DB. This MHDO is good for benchmarking purpose. You would need to address timeliness and PHI. Particularly timeliness. We would hope for monthly feed and then turn it around within 24 hours.

- There must be careful evaluation of the roles of the actors—state has regulatory requirements; I think it is the ultimate response of the providers to have and use the tools with appropriate regulatory oversight. There is a public perception and costs considerations. State agencies have tried to keep the people within the regulatory boundary but not regulate how you deliver the care. This can get the state pretty close to regulating how you deliver the care.
- One of our most significant challenges is that HIN does not own the data. Issue is we have privately owned data, and within partnership the question of appropriate data use that benefits all and does not threaten anybody. We are focusing on E H R being the source of the clinical data. By the end of next year we will have over 95% of the Hospital (and their providers) data set. The ambulatory is taking a little longer. We are focusing heavily on FQHCs. We are the first HIE in the country nearing public health profiles (CDC) by running our data through systems including the federal POPHealth. All data is de-Id. We will be able to send data to Maine CDC.
- Multiple issues are data warehouses that are cropping up. And then we have the APCD. We need to catalog this and the Legislature is aware of all of these cropping up.

Theme 2: Implementing technically-sound and scalable Data Processing Structures and Protocols that permit timely, accurate, and cost effective submission and dissemination of pertinent health care data (administrative and clinical).

- Timely access to all payer data is necessary to support system transformation. All payer data from commercial and public payers should be available at least quarterly to users. Data on a subset of patients is insufficient to facilitate population health management. Data that is not current does not allow for effective and timely interventions to change care.
- Medicare data is not available in a timely/usable manner
- Data available for the patient origin report is often not timely
- Hospital Cost web-site is not maintained and up to date,
- Problems with the quality of the Maine Care data made some of it unusable, resulting in only getting old data (2006) for other pieces. Delays in the availability of the discharge data are a constant frustration. The process of resulting the data and getting waivers for public use was time-consuming and caused a few other delays.
- The data is not very useful without Medicare and MaineCare data. To the extent that this is in the control of MHDO, a quicker turnaround time for updates is needed.
- The procedure for ordering data from the Maine Health Data Organization was fairly easy, however after several different runs, the data was still unusable.
- Data dictionaries are hard to find. Needed some assistance to find the right reports and

files.

- The complex role of data submitters is not well understood by health data stakeholders. There are significant costs and limitations to what can be provided and when.
- Ensure a feedback mechanism through which submitters can verify their own data, as it exists as the output of the APCD.
- A data submitters working group should be convened to help develop common data collection standards and procedures including what should be collected, how often, and the best approaches to continuous improvement of data quality.
- There is substantial cost associated with providing health data. In Maine, one of our Plans estimates the cost of programming a single change to a single data element, and there are several thousand across multiple platforms, at \$10,000. These operational costs are in addition to the annual assessments paid by carriers and providers that, along with modest income from data sales, fund the MHDO.
- There are systemic limitations to claims data in terms of both accuracy and timing that need to be acknowledged and understood.
- Not real time – only 50% of claims are adjudicated within one month of service provided, additional 35% in second month. The current release schedule of 90 days after close of quarter already requires monthly submissions from carriers.
- Limited outcomes data such as labs and radiology results.
- Lack of costs data at the claims/service level for capitated services or other special payment arrangements such as bundled payments or DRG payments.
- Data accuracy – up-coding, bundling and unbundling number to process a claim. Therefore, submitters should only be required to pass through the NPI submitted on the claim.
- NPI issues – NPI not available for all servicing providers on claims, NPI “confusion” between individual practitioners and billing practices, inaccurate NPIs on claims. Carriers may not need an NPI.
- Support broad based agreement among the states on a consistent set of data elements and formats for collection. Greater harmonization will enable increased automation through system programming increasing timeliness and efficiency. From a research and data integrity perspective, it also allows better comparisons across states, regions and populations.
- Data submissions from carriers should be limited to those elements utilized by carriers for the payment of claims. Seek out the best access point for additional data. For example, carriers do not typically need the middle initial of a provider’s name in order to pay claims. It makes more sense to collect this information directly from providers. For non-payment essential fields, submitters should be only required to pass through what the provider submits and not be required to interpret, correct or enhance provider submitted fields.
- Health Plans need comprehensive, clear and detailed messaging around which fields are

causing their files to fail and why. The current data submission system is iterative and uses a serial editing process causing timely and expensive delays and an enormous volume of unnecessary communication. If problems can be addressed and understood simultaneously then increased efficiency could be realized, and the time and expense for all could be better managed.

- Expedite the data submission process by identifying all the issues with a data file at once. Upon submission, carriers should quickly receive one report back detailing all the errors or problems with their data files. In this way, multiple issues can be addressed simultaneously and much more quickly, reducing resources and time required for the DQ Pass to be achieved. Where automated error messages frequently generate questions, messages should be revised to better explain the error.
- Changes to thresholds need to be systematized so that they are set with input from submitters and occur on a predictable annual schedule with adequate notice. The current approach relies heavily on the subjective views of a few and needs to be formalized. In this way, agreements from previous years can be formally tracked and recorded and all parties are saved the unnecessary hassle and additional expense of repeating requests and justifications. From a data quality perspective, thresholds of 100% are not realistic and have no place in the data submission standards.
- In cases where there are systemic issues that prevent the meeting of particular thresholds, then a permanent waiver or twelve month waiver period would be appropriate. It is resource intensive to have to reapply for the same waiver repeatedly. When a systemic issue will not change, Maine's approach of allowing adjustments month by month, rather than for a longer period should be altered to save time and resource expense for all. An example of this could be ancillary coverage, which rarely if ever has a billing provider; if the industry practice does not include use of a billing provider, why not permanently except this type of file from this requirement instead of requiring an annual renewal of a variance?
- Other efficiencies could be achieved by experimenting with ideas such as advance applications for threshold adjustments, so the new standard would already be in place when a file is submitted. Additionally, better files could be maintained about why and when different carriers requested adjustments. This would allow easy renewals without a new application process each time. Our plans report that NH has permitted advance threshold adjustments but Maine has not. Further, Maine requires that carriers "prove" there's still a problem each time. A better balance must be struck between Maine's desire to require carriers to provide the highest standard of data and the cost, use of limited IT resources and burden to everyone (not just the plans) associated with doing so.
- Maine should consider whether there are some data elements that are more important than others. Prioritizing data elements would help the parties focus on those that are most important. Health information is needed by different constituents and different

delivery rates. Patient data most frequent, analytical/financial data less frequently.

- There are several issues similarly impacting most if not all of member plans. In these cases where there seems to be an industry wide challenge, Maine should seek to explore ways of addressing these problems using a centralized approach. For example, several plans are facing challenges around the provision of prescriber identification data. Can a solution be devised where Plans pass through to the MHDO what they receive on claims and the MHDO or their vendor crosswalks that information to a centralized database they maintain from the PBMs? This is a far more practical approach than asking all submitters to develop separate and expensive solutions to a similar problem. This is not to say that we take the increase in assessments that would result from an approach like this lightly, but rather, that we recognize the value of having one system funded by all assessment payors collectively. For each submitter to fund a “fix” would be impractical, cumbersome, and unnecessarily expensive.
- Clinical data integrated with claims data to support ongoing care process improvement and efficiency efforts
- Inclusion of Medicare and Medicaid data that are up to date and accurate
- Pharmacy and BH data is inconsistent across payers.
- The hardest part of the quarterly reporting process is to line up the charge systems data lined up with event of care. Who, what diagnosis, and which are multiple systems in the hospital.
- Important to have a master provider and patient index (slide 8). MHDO’s RFP is around master patient and provider index. So we need to make sure that we don’t duplicate efforts and systems.
- Provider centric data is insufficient to provide the type of data needed to parse into episodes. For example, coronary at hospital; what we didn’t know was who went to rehab or nursing home or saw PCP twelve times in the next year.

Theme 3: Balancing Consumer Privacy considerations regarding the safeguarding and disclosure of Protected Health Information (PHI) with the societal imperative to drive higher quality and more affordable health care.

- Expansion raises the potential for poor policy decisions to be made about patient privacy, confidentiality, consent, notice, and control.
- Medical information is arguably the most personal and private source of data about us as individuals. In our work on health information technology, we continue to come back to the importance of informed consent. Fundamentally and consistently, patients should be aware of and have an opportunity to decide who has access to their medical information. That includes testing, diagnoses, treatment notes, payment and billing information, and anything else that is personally identifiable.
- Both doctors and patients worry that their medical data will not be adequately protected. They have good reason for concern. The familial, financial and professional

ramifications of inappropriately exposed health information could be devastating. And the larger and more comprehensive these databases become, they not only arguably become more valuable to patients, health professionals and administrators, they also become more vulnerable to thrill hackers, those seeking to commit medical identity theft, unscrupulous employees, and others.

- Concern about inadequate sharing or protection of health information can also lead patients to put off seeking care – leading to potential health consequences for that individual and fiscal costs for the rest of us. Imagine discriminatory review by insurance companies or potential employers so they can avoid paying for people who might be expensive to insure or employ.
- While there may be value to expanding uses of the MHDO database or to linkage with other databases, these decisions should be made with patient’s rights at the fore. Often those doing the hard work of providing us with healthcare get so excited about increasing efficiency or improving coordination of care that patient notice, privacy and consent can get lost.
- As patient advocates and defenders of personal privacy, we urge continual focus and commitment to privacy, confidentiality and security. Patient rights must be the highest priority in Maine’s electronic health information system, and we hope the State will continue to demonstrate meaningful commitments to patient privacy.
- We need to be very careful in protecting personal health information. However, we also need to be very vigilant about making sure data is being used to improve the health of Maine people.
- Patient identified data must be included but identifiable only at the patient/provider level to allow providers to effectively improve care for their patients. Identified data enables the combining of different data sources to allow a meaningful and longitudinal understanding of utilization, care patterns, and outcomes.
- Access to PHI data (by appropriate sources and with appropriate protections) to support ongoing projects.
- Health care providers need data with personal health information in a HIPAA compliant way so they can use it to improve care for those patients they are treating. Right now we have providers willing to take responsibility for the quality and cost of their patients and they don’t have good data readily available. I hear words like “betrayal” and “tying our hands behind our backs” from providers
- Within PCPs we may be able to only look at 10-15% of population. We cannot look at population data from a longitudinal basis because of the lack of data. Though I believe we need to be absolutely careful of PHI, the overall public good requires us to identify and implement standards so we can have PHI, have it timely, and need access to the PHI in the APCD. We will not be able to do the work that needs to be done if we do not do this.

Theme 4: Establishing mechanisms to ensure that consumer/stakeholder engagement and feedback is requested and prioritized to ensure value is being derived from the APCD.

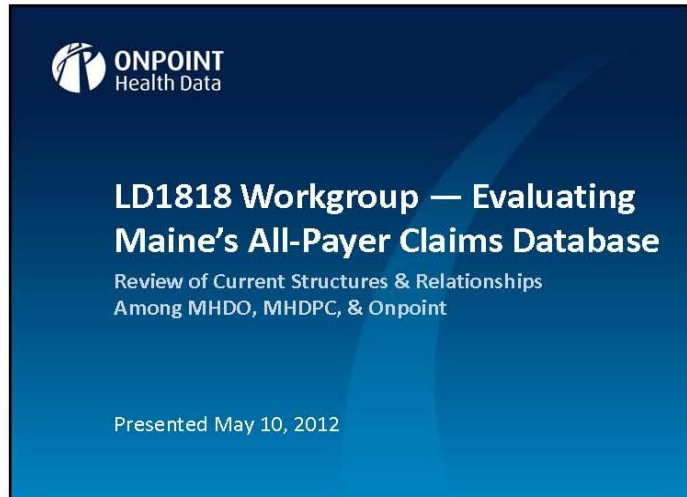
- Simple straight forward information that is important for patients making a choice of healthcare providers is important.
- Make consumers more aware that the data is available, and make it free to healthcare consumers. Media attention and/or information given out at facilities would help. Make available data simple to understand and easily accessible. Consumers do not understand terms like “4 infections per 1000 patient days”. Put it in an easily searchable format online.
- My use would be for personal use and to help consumers to make wise choices of providers for themselves. My consumer advocacy groups would also use the data to help consumers. Publication of data is also an incentive to facilities and providers to a improve quality and safety in their practices. When public data is available to all, then it makes healthcare providers accountable and transparent. Public pressure is often what it takes to motivate improvement.
- User friendly websites that can be found through key word searches on the internet would be useful. I would like to see those providing health insurance or medical services sending people diagnosis specific information and helpful hints. Also referral information should be available for an individual's primary health provider when a new diagnosis is given. For most people where they are first told that they have a medical problem is a "teachable moment".
- Everything! I want to know who, what, where, when, and why! Then I want to know how much it is going to cost me out of my own pocket. I am a thorough healthcare consumer. I question what medication I am being given, the pros and cons of this medication vs. another and the most effective form of delivery. When tests are ordered, I want to know why and what information is going to be learned. I will refuse anything I do not feel is appropriate and am lucky to have a provider who works with me.
- I am a true fan of online resources, reliable and proven ones. My provider is also an excellent resource. There are many community resources that I am lucky to know about as a result of working in mental health and now a community health center.
- The process has varied depending on what information I was seeking. Sometimes I have been successful and sometimes I have had to change what I was looking for in order to find any success at all.
- I am, once again, shocked to find that the two hospitals in my area are some of the most expensive in the state. I have had some of the procedures listed on this site. It makes me feel like my insurance company was swindled and, in return, so was I in terms of the co-pays I had to pay out of my own pocket!
- There are too many people who need services and the wait for appointments is too long. Health literacy is a huge factor. Materials are written far above the level of the

education of the people served so they cannot benefit. Many cannot read at all. Creating a health navigation or patient advocacy program within the MaineCare system is ESSENTIAL not optional! The people served by this program, for the most part, are not good healthcare consumers but are some of the biggest consumers of healthcare!

- Knowing there is a physician/clinic available 24/7 if I need care, to include but not limited to an E.R. Knowing that person has access to my medical record.
- Whether my care is covered by my insurance. If I have no insurance, cost of care. If I have no insurance, will I receive care
- Health status measures, rates of hospitalizations, emergency room visits, some interest in quality of care related measures, county, public health district and state levels, oral health, mental health, physical health.
- Discharge database (inpatient and outpatient), emergency room visits database, All Payor Claims database, Quality of care (HAI) data.
- Possible analysis of integrated care grantees
- Possible analysis of payment reform grantees
- More clinically relevant, real-time data that goes beyond claims
- Providers are going to need timely access to clinical data going into the future
- Clinical and Administrative data are going to have to be integrated in the future
- Consumers need a reliable source of information/data when they are choosing where to get their healthcare. Public reports on healthcare acquired conditions, such as HAIs and medical errors, ulcers, falls and other problems are extremely limited in the State of Maine. I was asked recently to provide reports from my state to the NEVER and CU groups. The sentinel events report was outdated and inaccurate, the HAI report was mostly process measures and only CLABSI and MRSA screening compliance results were available, and there were no detailed reports on other preventable errors or injuries and readmissions
- There is currently no detailed public data available to consumers on specific surgical complications for specific procedures. SSI on only Abdominal Hysterectomies and Colon surgery will be required by the Feds this year. This is extremely limited information. Patients should be able to access information on their specific condition, at their preferred Hospital, and find out exactly how many SSIs there were in the previous year. Patients are expected to trust and rely on their doctor's or Hospital's word that "there aren't that many". While that may be comforting to some, an educated consumer would want to confirm that for their own safety.
- Data on other preventable medical and surgical errors, adverse events and HAIs should also be available to healthcare consumers. I can get more information on a car service business than I can from my local hospital
- There is no ability to match up claims data with other increasingly available data (e.g. clinical, health risk, functional status, etc.) and
 - used by providers for improving care for patients for whom they are responsible

- used by purchasers and the public (using de-identified data) to help assess the value of the care they are receiving and to help guide people where they can receive the best value care
- Health care providers need to focus on improving the health of people. This includes health risks like smoking, nutrition, exercise, etc. that put people at risk for future problems as well as how they are functioning in life (i.e. fulfilling roles and responsibilities at home, in the community, at work, and in leisure time). These will be measured in the future and if combined with claims and clinical data can give health providers a better picture of how to improve the health and quality of life of the people they are responsible for. By also making this de-identifiable data available, it helps to find and publicize best practices, helps providers see how they are doing and could do better, and allows people to make choices of which providers they would like to go to.
- Meaningful cost of care data to support employees and families in the purchasing decisions
- Transparency into hospital costs to allow for assessment of systemic “right sizing” based on community capacity and fixed cost analyses
- Transparency into critical quality measures such as sentinel events by hospital
- I hope that we address in the 1818 group whether this web information should continue to be posted, or is it duplicative of payer info.? We have approximately 20 more to post.
- In Maine very little done to data set to make it valuable to users. Other states do that. Small health systems would have a hard time putting this together. What additional things could we do to make data set more user friendly. The MHDO RFP moves us in the right direction—it could do value added and save money. One of the frustrations is that different organizations use different approaches and tools which make it more difficult.
- We should consider financial incentives for the use of the systems. We do something to move that work flow. Policy is probably what is needed to change.
- How do you bring the consumer into the equation to give them value? That should be a recommendation from this group and that is perhaps another committee.

Appendix C: Factors Influencing All Claims Payer Database Timeliness



Background – Onpoint Health Data

- 35+ years as independent, nonprofit
- Founded by MHA, MMA, MOA, BlueCross, MCD, Bingham
- Maine-based – Manchester, Portland offices
- 34 staff – programmers, analysts, health data specialists, project managers, other health IT professionals
- 2 core services
 - Data Management – Claims and hospital encounter data aggregation, cleansing, preparation
 - Health Analytics – Expert in claims-based reporting, analytic tools (groupers, risk adjusters, etc.), linking with other data sets, online reporting solutions

ONPOINT Health Data | LD1818 Workgroup – Evaluating Maine's APCD System 2

Background – Onpoint Health Data

- Clients
 - Data Management
 - All-Payer Claims Database – ME (MHDO), NH (DHHS/Ins. Dept.), VT (Dept. of Financial Reg.), MN (Dept. of Health)
 - Hospital Encounter – NH (DHHS)
 - Health Analytics – VT (Dept. of Financial Reg., Medicaid, Blueprint for Health), NH (Medicaid), ME (State of Maine Employees, ME CDC, Mercy, MaineHealth, Franklin, other provider organizations)

Background – Onpoint Health Data

- Track record of leadership, innovation
 - First of its kind, multi-payer claims database for MHMC
 - Data/analytic support for Wennberg / Dartmouth Institute variation work
 - Creation of first multi-state APCD database to support regional variation
 - Partnered in development of HealthInfoNet

Roles & Functions in Developing, Maintaining ME's APCD

- Two partners in Maine Health Data Processing Center (a public-private partnership)
 - **Onpoint** – Technical partner; brought experience developing a multi-payer claims database
 - **MHDO** – Regulatory partner; brought statutory authority, rulemaking experience in the collection and release of hospital data

Roles & Functions in Developing/ Maintaining Maine's APCD

Onpoint Health Data	MHDO
Payer communication, on-boarding	Rulemaking – data collection, release
Payer registration – initial, ongoing	Payer compliance
Secure upload and PHI encryption	Submitter role – Medicare (including mapping to APCD format), MaineCare
Data collection, validation in conformance with state regulations	Loading, warehousing data
Data specs, submission schema, reporting systems maintenance	Extracts to approved users
Master Person Index	Administrative – fee assessment to payer s/providers, users; board support
Master Provider Index	
Extract preparation – qtrly to MHDO	

Impact of Other Organizations on Performance & Timeliness

- Organizations impacting APCD timeliness

Organization	APCD Role	Target
Payers	Extract enrollment, claims from data warehouse to Onpoint	30 days + 15-day grace period
Aggregator (Onpoint)	Intake, standardize, QA data; extract to MHDO	30 days
Regulator (MHDO)	Load/QA extract, prepare for release	15 days
Total		90 days

Impact of Other Organizations on Performance & Timeliness

- Current availability of data through MHDO

Payer	From	Through	Target	Status
Commercial	Q1, 2003	Q4, 2011	Q4, 2011	On time for the last 18 months
MaineCare	Q1, 2003	Q3, 2010	Q4, 2011	Molina implementation caused problems with eligibility, other data; corrected files expected soon
Medicare	Q1, 2003	Q4, 2006	Q4, 2010	07/08 in house; mapping complete; currently receiving test files

Impact of Other Organizations on Performance & Timeliness

- **Payers** – Issues impacting timeliness, performance
 - Percent files overdue (past 30-day deadline): 36%

File Type	% Late Q3 2011	% Late Q4 2011
Eligibility	34%	32%
Medical	53%	47%
Rx	42%	34%
Dental	35%	27%

- Percent of files failing Onpoint DQ/validation edits: 37%

Impact of Other Organizations on Performance & Timeliness

- Direct vs. indirect interface with payer
 - Commercial plans – Direct, no delay
 - Government – Indirect, multiple parties involved; causes delay
 - MaineCare – MHDO as liaison
 - Medicare – MHDO as submitter
 - » Application, DUA process
 - » Mapping, programming to APCD format
 - » Available once/year, Final Action Files

Impact of Other Organizations on Performance & Timeliness

- **Aggregator (Onpoint)** – Issues impacting timeliness, performance
 - Downstream from submitters – Issues that impact them impact Onpoint, too
 - Volume of small payers – 50-lives threshold
 - Last minute requests – Short-circuiting processes
 - Indirect relationships
- **Regulator (MHDO)** – Issues impacting timeliness, performance
 - Resource constraints

Factors Impacting Quality, Timeliness, & Output

- Data collected
 - Eligibility – Medical, pharmacy, and dental
 - Medical claims
 - Pharmacy claims
 - Dental claims
- Collection frequency
 - Monthly for 66% of companies (including MaineCare)
 - Quarterly for 20% of companies
 - Annually for 14% of companies (including CMS)

Factors Impacting Quality, Timeliness, & Output

- Volume

Metric	ME	NH	VT	MN
Submitters	149	71	77	78
Data volume/year	175M	115M	70M	525M
Files processed/month	400	175	200	200
Data types	EMPD	EMPD	EMP	EMP
Public payers – Medicaid	X	X	X	X
Public payers – Medicare	X			X

Factors Impacting Quality, Timeliness, & Output

- Administrative data set – Volume, diags, \$; no outcomes
- Delays with government claims data
- Excluded activity
 - Uninsured, workers' compensation, VA
 - Outcomes/results from testing
 - Premium information, capitation/admin. fees, etc.
- Payer compliance with state rules
 - Acceptance criteria
 - Data quality edits

Factors Impacting Quality, Timeliness, & Output

- Lack of standards
 - Non-standard ways of processing, storing data by payers
 - Challenges
 - Master Provider Index – NPI took effect in '07; not fully or consistently implemented by submitters
 - Master Person Index – Encryption of PHI, inconsistent population of key identifiers (e.g., SSN)
 - Hospital owned practices – Billing at tax ID, provider-based reimbursement rules
 - Bundled billing – Loss of service-level detail

Factors Impacting Quality, Timeliness, & Output

- Infrastructure
 - Processing capacity – More than 100M claims and eligibility records per month
 - Performance – Manage and warehouse more than 10TB of APCD data on state-of-the-art Oracle databases and advanced Storage Area Networks
 - Security – Encryption technologies at both the file and field levels plus advanced firewall capabilities to ensure HIPAA compliance

Potential Changes to Improve Timeliness, Reliability, & Quality

- Reduce volume of submitters
 - Smaller submitters – Quarterly, annual filers
 - Dental submitters – Few requests for data
- Shift organization roles, free up resources
 - Streamline/simplify MHDO compliance process
 - Establish a direct relationship with MaineCare
 - Outsource Medicare mapping, integration

Potential Changes to Improve Timeliness, Reliability, & Quality

- Enhancing database as analytic resource
 - Increased value-add – Elements/flags, groupers
 - Consolidation claims
 - Increase data scrubbing
- Improve MPI
 - Person – Advanced clustering, improving quality of underlying elements
 - Provider – Intake of provider files, adding street address, adding physician-to-group crosswalk

Potential Changes to Improve Timeliness, Reliability, & Quality

- Harmonization efforts with other states
 - Demand for regional comparative analysis
 - Can't track patients from state to state
- Linking with other data sets
 - HealthInfoNet – Clinical outcomes, other
 - Hospital encounter
 - Birth, death, immunization registries

Potential Changes to Improve Timeliness, Reliability, & Quality

- Rule changes
 - SSN threshold increased
 - Expanding from *residents only* to *residents + policies written*
 - ICD-10 conformance
 - Provider file and/or street address submission

Questions or Follow-Up?

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Appendix D: Maine Health Data Organization Program

1/24/2013



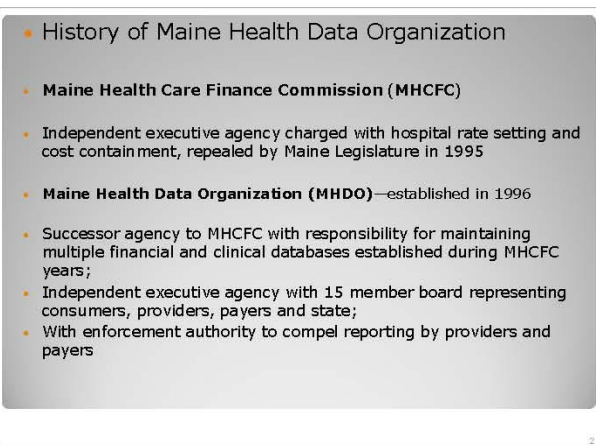
**Maine Health Data
Organization**

MHDO's Role and Functions in Developing, Maintaining
and Distributing an All Claims All Payer Database

Presentation to LD 1818 Workgroup
May 10, 2012

Anne L. Head, Vice Chair, MHDO Board of Directors

3



- History of Maine Health Data Organization
- **Maine Health Care Finance Commission (MHCFC)**
- Independent executive agency charged with hospital rate setting and cost containment, repealed by Maine Legislature in 1995
- **Maine Health Data Organization (MHDO)**—established in 1996
- Successor agency to MHCFC with responsibility for maintaining multiple financial and clinical databases established during MHCFC years;
- Independent executive agency with 15 member board representing consumers, providers, payers and state;
- With enforcement authority to compel reporting by providers and payers

2

1/24/2013

- **Maine Health Data Processing Center (MHDPC)—**
- Public-private partnership established in 2001, designed to provide data processing services in partnership with MHDO.

3

- **MHDO All Payer/All Provider Claims Database (APCD)**
- Established by MHDO in 2003 as “first in nation” APCD, intended to capture claims data from:
- All payers including commercial carriers and public payers (Medicaid and Medicare)
- In partnership with DPC/Onpoint.

4

1/24/2013

- **APCD contains:**

- Paid medical, dental, pharmacy claims files for all covered services rendered to publicly (Medicare Part A, B, C, D and Medicaid) and privately insured Maine residents
- Eligibility / membership files
- Health care service provider files
- Standard format utilized:
 - HIPAA standard codes
 - HIPAA transaction set data elements

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- **APCD Data Collection**

- The first step of the process is **data collection** from source system.
- Medicare data is sent to MHDO by Center for Medicare and Medicaid (CMS).
- The Medicaid data is sent to MHDO by Office of MaineCare Services (OMS).
- Commercial claims data is sent to Onpoint by all payers who have 50 or more members in Maine. Onpoint combines the data from each of these sources and sends it to MHDO. This data is then made available to consumers and stakeholders.

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- **Data Transformation**

- **Medicare Data**

- The Medicare data is purchased by MHDO from CMS and received annually. There is 2-3 year delay in availability of data from CMS. The most current data MHDO has received is for year 2008. It is currently in the data transformation process.
- Medicare data received by MHDO is converted into a format that is compatible with commercial claims data and sent to Onpoint. The goal is to complete this conversion in about 7 days; however it is dependent on MHDO receiving the data in correct format. Once the data is received by Onpoint, it is merged with other commercial claims and Medicaid data. Onpoint requires 30 days to complete its processing. Once the combined data is received by MHDO, it needs another 30 days to make it available for reporting and to other stakeholders.
- This process is different from commercial because CMS sends the Medicare data in a format that is different than commercial claims data structure. MHDO converts into a commercial consistent format before sending this to Onpoint.

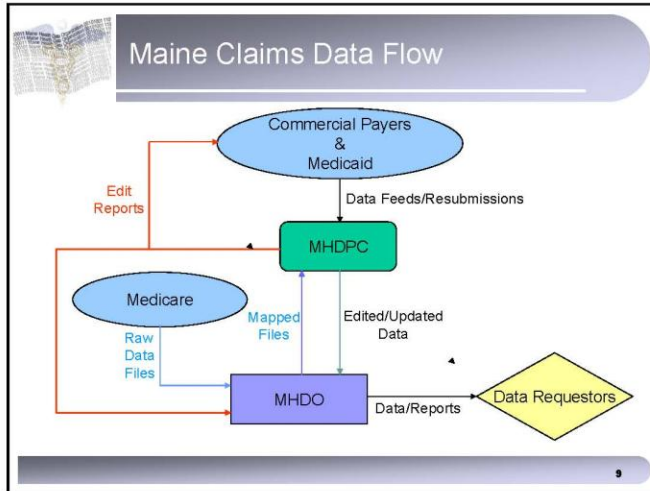
7

- **Medicaid Data**

- Medicaid claims data is sent by OMS through one of two paths to MHDO for transformation.
- 1/2003-8/31/2010 OMS to Muskie to MHDO to Onpoint
- 9/1/2010 and after—Unisys/Molina/DHHS to Onpoint
- Once the data is received by MHDO it is converted into a format that is compatible with commercial claims data. Once the conversion is complete the data is sent to Onpoint. MHDO's goal is to complete this conversion in 7 days. Once the data is received by Onpoint, it is merged with other commercial claims and Medicaid data. Onpoint requires 30 days to complete its processing. Once the combined data is received by MHDO, it needs another 30 days to make it available for reporting and to other stakeholders.

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1/24/2013



- Maine Health Data Organization in 2012
- Statutory mandate to:
 - Maintain financial and clinical health data for use in policy development
 - Adopt rules governing data collection
 - Adopt rules governing public access to data
 - Adopt rules for sanctions for failure to comply
 - Set fee schedules and assessments on health care facilities, payers, including third party administrators,
 - Respond to requests for data in timely fashion

1/24/2013

- Produce clearly labeled and easy to understand reports reflecting quality of care and price comparison that are publicly accessible on MHDO website
- 21 member board (5 current vacancies) 5 MHDO subject matter staff, 4 State Office of Information Technology technical staff
- MHDO Databases in addition to APCD
 - Hospital inpatient
 - Hospital outpatient
 - Hospital emergency department
 - Non-hospital ambulatory services (1990 – 2004)
 - Hospital financial
 - Hospital organizational
 - Quality data

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- **Future Vision of MHDO**
- Recent board retreats have culminated in plans for:
 - Restructuring to significantly reduce number of board members while retaining stakeholder diversity and balance;
 - Recommitment to maintaining agency's independent status;
 - Refocusing attention on improvements in the current data transformation process using state RPF process;
 - Enhanced communication with partner agencies, stakeholders and end users;
 - Immediate appointment of an interim executive director;
 - Initiation of search for permanent executive director.

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- Organizations that impact MHDO's performance
- MHDO Critical Partners
 - **Commercial carriers**—provide timely, accurate claims data submitted to Onpoint pursuant to submission schedule
 - **Onpoint/DPC**—accepts commercial claims data, processes it in a timely manner and retransmits data to MHDO, according to mutual agreement between the two organizations.
 - **Office of Information Technology**—provides expert project management support and systems support for technical projects. OIT staff and MHDO staff work in close collaboration and partnership on all projects.

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- **Department of Health and Human Services, Office of MaineCare Services (Medicaid)**

Data Flow summary:

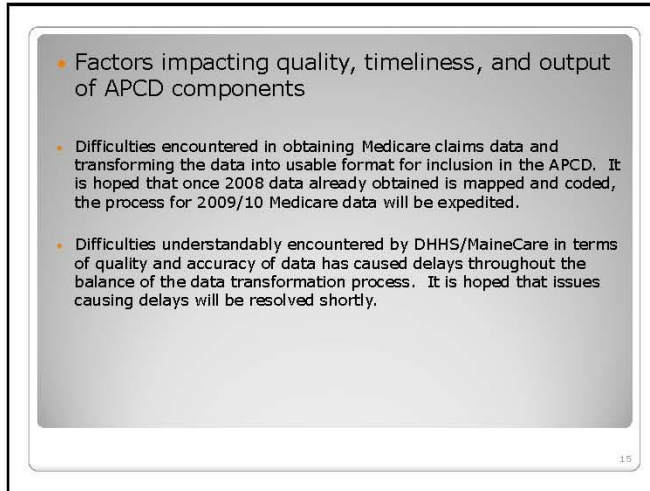
1/2003-8/31/2010 OMS to Muskie to MHDO to Onpoint
9/1/2010 and after—Unisys/Molina/DHHS to Onpoint

Federal CMS (Medicare)

Claims data is purchased by MHDO and is mapped and coded by MHDO/OIT staff before transmitting it to Onpoint for editing. There is typically a two year lag time on Medicare data. Additional resources of MHDO, Onpoint and OIT have been deployed to expedite more current data being made available to end users.

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1/24/2013



- Factors impacting quality, timeliness, and output of APCD components
 - Difficulties encountered in obtaining Medicare claims data and transforming the data into usable format for inclusion in the APCD. It is hoped that once 2008 data already obtained is mapped and coded, the process for 2009/10 Medicare data will be expedited.
 - Difficulties understandably encountered by DHHS/MaineCare in terms of quality and accuracy of data has caused delays throughout the balance of the data transformation process. It is hoped that issues causing delays will be resolved shortly.

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Appendix E: Inventory of Engagement Mechanisms



Maine Quality Counts - Consumer/Patient Engagement Framework

Patient/Consumer Interest	Patient/Consumer Role	Options for Involvement	Supports Needed	Key Characteristics/ Skills
<p>Level A:</p> <ul style="list-style-type: none"> • Improve one’s own health • Improve health of family member 	<p>Active partner in care</p>	<ul style="list-style-type: none"> • Engage in self-management, goal-setting • Participate in shared decision making • Participate in Living Well program • Participate in support group • Participate in health-related social networking site • Know how to access your medical records and make changes if required • Increasing progression on the Behavior Engagement Framework • Use of personal health record or other tracking 	<ul style="list-style-type: none"> • Evidence-based guidelines on recommended treatments, goals (e.g. Pathways) • Living Well program (group, online) • Information on action steps, trusted support programs • Information on how to access health records and how to make changes/edits 	<ul style="list-style-type: none"> • Self-awareness re: personal role in managing health • Ability to identify, communicate treatment preferences • Willingness to communicate with care team • Ability to track and organize personal health records and information

Patient/Consumer Interest	Patient/Consumer Role	Options for Involvement	Supports Needed	Key Characteristics/ Skills
		tools		
<p>Level B:</p> <ul style="list-style-type: none"> Get information to make informed choices about care 	Active partner in care	<ul style="list-style-type: none"> Access GetBetterMaine website and other info on health care quality, costs Help others access information Understand issues of healthcare safety and advocate with providers to adhere to safety guidelines 	<ul style="list-style-type: none"> Trusted information on health care quality & costs Resources to answer questions 	<ul style="list-style-type: none"> Desire to seek out information Ability to distinguish between valid & erroneous information sources Ability to discuss choices, ask questions
<ul style="list-style-type: none"> Level C: Work with others to help improve their health 	Peer supporter	<ul style="list-style-type: none"> Serve as Living Well instructor Serve as peer-to-peer support, mentor Understand Behavior Engagement Framework and how you can assist others with specific behaviors Serve as patient navigator in your health care system 	<ul style="list-style-type: none"> Training programs Peer support Patient navigation training 	<ul style="list-style-type: none"> High degree of empathy Good communicator Ability to maintain confidentiality
<p>Level D:</p> <ul style="list-style-type: none"> Work directly with health care providers to help improve the 	Practice Change Advisor	<ul style="list-style-type: none"> Work with primary care practice redesign team (“Practice Partner”) Serve on health care 	<ul style="list-style-type: none"> Training programs (e.g. mtg facilitation, leadership, 	<ul style="list-style-type: none"> Commitment to improve care and value team goals over individual interests Ability to maintain

Patient/Consumer Interest	Patient/Consumer Role	Options for Involvement	Supports Needed	Key Characteristics/ Skills
delivery, quality, experience of care		Patient Advisory Council (e.g. for primary care practice, hospital) <ul style="list-style-type: none"> • Participate in provider committees 	knowledge, QI methods) <ul style="list-style-type: none"> • Peer support & coaching 	confidentiality <ul style="list-style-type: none"> • Desire to gain knowledge re: health care quality • Comfortable articulating patient insights & bringing patient feedback to improvement team • Receptive to views of others • Good communicator
Level E: <ul style="list-style-type: none"> • Work with stakeholders to drive system, policy, payment changes to transform care 	Policy advisor, champion for change	<ul style="list-style-type: none"> • Serve on QC Board • Serve on QC Consumer Advisory Council • Serve on HIN Consumer Committee • Get involved in meetings with local providers • Participate on State Workgroups • Participate in local community forums on healthcare quality and cost 	<ul style="list-style-type: none"> • Training programs (e.g. mtg facilitation, leadership, knowledge, QI methods) • Peer support & coaching 	<ul style="list-style-type: none"> • Commitment to improve care and value team goals over individual interests • Foundational understanding of health care quality • Ability to seek out & synthesize information on complex topics • Receptive to views of others • Excellent communicator • Ability to problem-solve in inclusive manner that addresses issues from myriad of perspectives

CONSUMER ENGAGEMENT NOTES

Citations (pages 25-26)

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Definitions

Consumer engagement:

Consumer engagement is defined by the actions individuals take to obtain the greatest benefit from the health care goods and services available to them.

[http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CDUQFiAA&url=http%3A%2F%2Fwww.carecontinuumalliance.org%2Ftheforum11%2FPresentations%2FConsumer Engagement Across the Health Care Spectrum.pdf&ei=ydkaUJm-](http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CDUQFiAA&url=http%3A%2F%2Fwww.carecontinuumalliance.org%2Ftheforum11%2FPresentations%2FConsumer%20Engagement%20Across%20the%20Health%20Care%20Spectrum.pdf&ei=ydkaUJm-)

[M5Kc8gTw4oDYDw&usq=AFQjCNFUqoij3Q](https://www.google.com/search?q=M5Kc8gTw4oDYDw&usq=AFQjCNFUqoij3Q)

Healthcare consumer

Actual or potential recipient and/or purchaser of health related goods and services such as a patient in a hospital, member of a health insurance plan, client of a behavioral health therapist, person receiving community support services from a social worker, etc.

Healthcare Consumer - Patient stakeholder Representative

Individuals who act, in a mission-oriented manner, to further the interests of patients and/or consumers, their primary emphasis being on the needs and interests of these patients and/or consumers. .

Appendix F: Legal Work Group Report

LEGAL WORK GROUP (LWG) PRESENTATION TO THE L. D. 1818 (CHAPTER 109) WORKING GROUP

August 16, 2012

INTRODUCTION

This document summarizes the work of the Legal Work Group (LWG) in response to a request by the LD 1818 Working Group about Protected Health Information (PHI). Specifically, the LWG was tasked with helping inform the Working Group on one of the four issues included in LD 1818:

3. Considering federal and state privacy and security laws regarding the use and release of protected health information, including policy and technical changes needed to allow increased access to protected health information and the feasibility of those changes;

This document is divided into five sections: I. Background; II. Organization of Presentation; III. Hierarchy of Laws; IV. Current Federal and State Laws and Rules; and V. Conclusion.

I. Background

Among other provisions, the 2009 HITECH Act created three initiatives: 1) The establishment of the federal Office of the National Coordinator for HIT; 2) The Medicare HIT Meaningful Use (operated and governed by CMS); and 3) The Medicaid Meaningful use Program (governed at the State Medicaid level with 100% federal funds for MU payments and 90% federal funds for State administration of the program).

The ONC required States that wanted to participate in the ONC initiatives, to establish an Office of the State Coordinator for HIT to oversee state HIT activities. In addition to the OSC, the ONC signed contracts with an entity within each state and provided funding to establish and operate a Regional Extension Center (REC). The RECs sign-up hospitals, and up to 1,000 primary health care professionals and entities, to implement an electronic health record (EHR) and participate in a health information exchange (HIE). In Maine, the ONC contract is with HealthInfoNet that established Maine's REC. HIN also used its exchange which had already been established as part of a pilot program in the mid-2000s as the HIE.

In 2010, the OSC was established by Executive Order (EO), which also named HIN's HIE the "HIE" under the ONC initiative. The OSC is now housed in DHHS. It is advised by a HIT Steering Committee (HITSC), an approximately 17 member Committee of stakeholders established in EO. The HITSC first established the Legal Work Group (LWG) in 2010 to help inform them on privacy issues. The LWG was again reconvened in 2012 for two purposes, one of which falls under the purview of the 1818 group--To help inform the 1818 Group on the question about Increasing Access to PHI. (The second purpose is to draft definitions and roles and responsibilities of a State Designated HIE which will be submitted for HITSC for discussion and a report to the OSC). The LWG has approximately 12 members, comprised of lawyers and other professionals from the State, healthcare organizations, consumers, and others.

With this background in mind, the LWG is making its initial report to the 1818 Working Group. Many LWG members believed it was important to state that they view the scope of the LWG as providing a factual review of the current federal and state laws and rules governing PHI. Then, if the 1818 Working Group desired to have specific scenarios examined, the LWG would provide a legal analysis of the specific scenarios. In that respect, the LWG would not make what might be termed "subjective recommendations." Rather, its analysis would be "objective and factual" in nature.

It is a challenge to inventory, analyze and report on laws and rules that govern PHI. They have been developed in a piecemeal fashion, and terms and definitions vary by law and rule and even in conversation. For example, some laws may use the term disclose while others use release or use. For these reasons, the documents being presented are an attempt to provide in the least complex way, a very complex subject.

II. Organization of Presentation

This presentation consists of several documents, including this summary document, definitions document, and several graphics and spreadsheets. Since this presentation revolves around "protected health information" (PHI) it is useful to define that term. The term PHI is from HIPAA requirements to protect all "individually identifiable health information" which is demographic data that relates to:

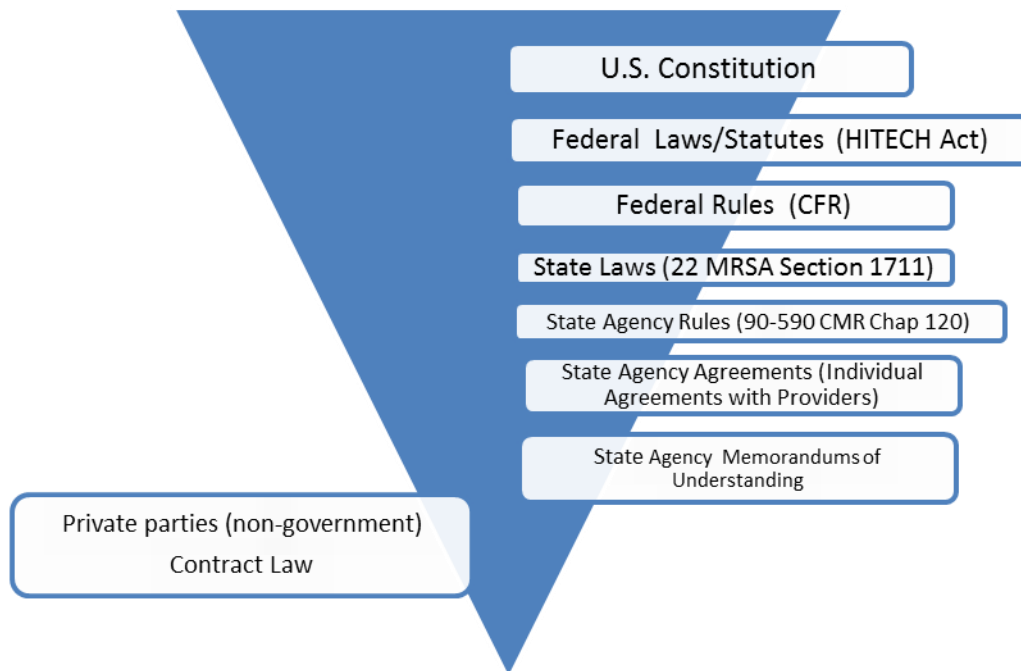
- The individual's past, present or future physical or mental health or condition;
- The provision of health care to the individual, or the past, present, or future payment for the provision of health care to the individual; and
- That identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual.

Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number).

1. Graphic and Detailed Grids (Spreadsheets). The graphic and spreadsheets are grouped into four categories of PHI: General Health (termed non-sensitive PHI); and Mental Health, Substance and Alcohol Abuse, and HIV (these three are termed sensitive PHI). The reason the LWG chose these categories is because for the most part, federal and state laws and rules treat PHI differently based on which one of these categories the PHI falls under. Then, the four categories of PHI are further delineated by the category of use: Informed Consent, Treatment, Payment and Operations (TPO); Public health; Fundraising; Research; and Marketing, because federal and state laws and rules treat PHI differently based on use.
2. Inverted Pyramids -- This is a very high level graphic that displays each of the four categories of information (columns) and the six basic uses of information (rows). "Allowed" disclosure of PHI is at the top of the inverted pyramid, moving down to the "restricted" disclosure and finally the bottom of the pyramid which is "prohibited" without patient consent. (Note: This document is intended as the general rule. It does not depict the exceptions to the general rule.)
3. Detailed Grid – This spreadsheet builds on the inverted pyramid document. The spreadsheet has two tabs: 1) Detailed (General Health, SA, and HIE) and MHDO and HIN/HIE; and 2) Detailed_MH (Shown under separate tab because Maine law differentiates between MH agencies and professionals who may provide MH services as part of their practices).

For each of the four pyramids, it "drills down" to show the federal and the State laws and rules that govern each categories of information (General Health, Mental Health, Substance and Alcohol Abuse, and HIV), and within the category, the laws governing each of the six types of information. It provides a brief summary of the applicability and a cite to the law. In addition, there is a column that is color coded to show "allowed" disclosure as green; "restricted disclosure" as yellow; and "prohibited without consent" as red. (Note: The color coding is intended to show the general rule. There are likely exceptions to the rule.)

III. Hierarchy of Laws



This diagram shows the hierarchy of law. Generally speaking, federal statutes (laws passed by Congress) and federal rules (Federal Agencies, under the authority of their federal statutes, make rules which generally apply across the board to all states), trump state statutes (laws passed by state Legislature) and state rules (state agencies, under the authority of their state statutes, make rules which generally apply across the board to all citizens/entities within their state). That is, if a federal rule contradicts a federal law, the law supersedes the rule. If a state law contradicts a federal law or federal rule, the federal law/rule supersedes the state law. If a state rule contradicts a state law (or a federal law/rule) the state law (or federal law/rule) supersedes the state rule. Some federal laws and rules permit states to ask federal agencies for a waiver, exemption, or federal agency action or permission to depart from the general law or rule. Absent that, it takes “an act of Congress” to change a federal law. To change a federal rule would require the federal agency to change the rule. State laws must be changed by Legislatures; state rules must be changed by state agencies.

Some federal laws/rules preempt state laws/rules altogether. This means that states must follow only the federal laws/rules and cannot make their own state laws/rules. Some federal laws/rules permit states to layer their own state laws/rules on top of the federal laws/rules, as long as the state law/rule is not inconsistent. For example, let’s

say that a federal environmental law states that the EPA must make a rule that is protective of shore land development. The EPA makes a rule in accord with APA provisions, that preclude a person from building a factory within say, 50 feet of a large river. The EPA law and rule allow states to provide more protection. So a state passes a law that prohibits development within 75 feet. The state law is legal because it provides more protection. (A state could not pass a law that only provides a 25 foot protection.) Federal rules must be made according to the federal Administrative Procedures Act (APA), and state rules according to the Maine APA. The APA governs the process and requires agencies to provide notice, allow comments, and to follow designated timelines. In Maine there are two types of rules: 1) Technical which allows the agency head to adopt and implement the rule; and 2) Major Substantive, which allows the agency head to provisionally adopt the rule but requires the rule to go to the Maine Legislature and follow the legislative bill process where the Legislature may vote to adopt, modify or not-adopt the rule. If the legislative votes to adopt the rule, the rule goes into effect. If the Legislature modifies the rule, the modified rule goes into effect. If the Legislature votes not to adopt the rule, the rule is void.

Statutes (laws) and adopted rules may be challenged in court. Federal rules are generally challenged in federal court; state laws and rules challenged in state court. In addition to statutes and rules, agencies may make policies and practices outside the APA process. These policies and practices do not have the same force of law as laws (statutes) passed by the Legislature or agency rules adopted under the APA. Agencies may also enter into contracts (enforceable under contract law), agreements (somewhat similar, but sometimes less formal than contracts) and memorandums of understanding (more of agreed upon expectations between the parties). The diagram above places these types or arrangements below that of laws and rules.

Entities that are non-government (private parties), must abide by federal and state laws and rules. In addition, contract and other types of laws provide supplemental legal parameters.

IV. Current Federal and State Laws and Rules

1. HIPAA

HIPAA is a federal law, that is supplemented with federal rules. It is the federal umbrella that governs all four categories of PHI. (General Health, Mental Health, HIV, SA) Having said that it only applies to what are called “covered entities.” (health plans either individual or group plans that provide or pay medical care costs; health care clearinghouses which are entities that standardize formatting which covers billing

services, repricing companies, community health management information services, value-added networks if they perform the standardizing services; and every health care provider regardless of size; AND who electronically transmit data). When PHI is used or disclosed to an entity that processes claims, data analysis, utilization review, and billing for covered entities, the entity is a "business associate" (BA) and requires a BA agreement (BAA) which requires the BA to comply with HIPAA.

The use or release or disclosure of de-identified data is not restricted under HIPAA which basically only covers PHI. If PHI is encrypted in a manner proscribed under HIPAA, or consists of a limited data set, or deemed de-identified by a statistician, it can be disclosed without consent.

HIPAA allows states to enact laws and rules that provide more protection than HIPAA. In addition, HIPAA permits states to have what is termed "contrary" laws for limited purposes such as laws requiring providers to report public health types of info, or a law requiring health plan reporting, such as for financial audits and for management. Changes to HIPAA statutes require an act of Congress.

2. Substance Abuse and Alcohol Abuse (Part 2)

In addition to HIPAA, the federal Substance Abuse and Alcohol Abuse (SAA) laws and rules govern SAA PHI. The federal SAA laws and rules preempt state law and rules. This means that states must follow the federal law and rules for Substance Abuse and Alcohol Abuse PHI. In addition to this federal requirement, Maine has laws and rules that state Maine must follow the federal law and rules. Changing the federal laws or rules around SA PHI would be the most difficult of any of the four categories. State laws and rules would also need changing.

3. Mental Health

Other than HIPAA, there are few federal laws and rules on mental health PHI. (Mental Health providers who participate in Medicare, are subject to federal Medicare Communities of Practice (CoPs) governing the privacy and confidentiality of patient information.) Maine does have state laws and rules, and those laws distinguish mental health agencies/professionals licensed by the State as MH providers from health care agencies/professionals who may provide MH services as part of their practices. MH providers have more restrictions on MH PHI than health care providers. Since MH PHI is governed by State laws and rules, from a legal standpoint changing them would be easier than attempting to change federal law or rules. Also note that Maine has had a series of consent decrees that would need to be considered.

4. HIV

Other than HIPAA, there are very few federal laws and rules on HIV. Maine state laws and rules govern HIV PHI, which are summarized in the HIV grid.

5. Maine Health Data Organization (MHDO)

HIPAA laws do not apply because MHDO is not a covered entity nor is it a business associate. Maine's Attorney General's office has advised MHDO that they are a Public Health Authority (PHA), a term created in HIPAA that allows providers and hospitals to submit PHI to the PHA.

MHDO is an independent State agency which means it is not an executive department agency (such as Department of Transportation, Taxation, DHHS). MHDO is governed by a board (consisting of representatives of public and private entities) under the auspices of being a comprehensive health database to improve the health of Maine people. MHDO has rulemaking authority, some of which are technical rules while others major substantive.

MHDO collects data on claims and finance (per rule, claims data) and in/outpatient, and specific quality indicators (per rule, clinical data). By statute, MHDO, under its vendor Onpoint, sends algorithms to payors who run their provider's data through the algorithm and then submit it to Onpoint who encrypts further and then sends it to MHDO. In this respect, it may be a double encryption.

MHDO must make some de-identified information available to the public and post it on the Web. In addition, entities may request data (in writing per MHDO rules) and requests are approved by Board. Data provided may be unrestricted (receiver may further disclose) or restricted (no further disclosure allowed) depending on the type of data. Most MHDO work is done under provider agreements governed by MHDO rules.

MHDO laws and rules generally do not permit the MHDO to disclose/release PHI. Unless the encryption that MHDO has performed is considered to make the data non-PHI, it is most likely that the MHDO law and certainly, MHDO rules would need to be changed, to allow the MHDO to release PHI.

6. HealthInfoNet and its Health Information Exchange

There are no specific federal laws on HIEs in terms of releasing PHI. There are a few State laws and rules that discuss the term “State Designated HIE” (SDHIE). Currently, by Executive Order, HIN’s HIE serves this capacity.

HIN is currently a non-profit non-governmental entity governed by a Board of Directors. It primarily deals in clinical data, and while neither HIN nor its HIE are covered entities, they are considered a Business Associate under HIPAA and enter into BAAs with covered entities. From a practical standpoint, HIN and its HIE are affected by HIPAA law. They also fall under General Health, Mental Health, Substance Abuse and HIV laws and rules.

Since HIN and its HIE are neither federal nor state agencies, they do not have rulemaking authority nor governmental enforcement authority. They have a practice of negotiating private agreements with providers that govern the exchange and release of PHI.

A State law enacted in 2011 (arising from work performed by the LWG), allows the exchange of PHI data as long as the HIE has an opt-out for general health information and an opt-in for sensitive health information (MH, SAA, and HIV). HIN’s HIE follows this opt-out and opt-in practice.

V. Conclusion

The LWG appreciates the opportunity to provide this legal review of PHI laws and rules. Should the LD 1818 Working Group decide to consider different scenarios, the LWG is prepared to provide further review and reporting on changes that would be required based on the scenarios presented.

DEFINITIONS AND GLOSSARY OF TERMS
For LWG Presentation to LD 1818 Working Group
August 16, 2012

1. HIPAA definitions:

Business associate: (1) Except as provided in paragraph (2) of this definition, business associate means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in §164.501 of this subchapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or

(B) Any other function or activity regulated by this subchapter; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in §164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such organized health care arrangement.

(3) *A covered entity may be a business associate of another covered entity. § 160.103*

Direct treatment relationship means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship. § 164.501

Disclosure means the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information. § 160.103

De-identified health information is health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. Information can be de-identified using statistical methods (45 C.F.R. § 164.514(b)(1) or by removing specific information set in the HIPAA rules (45 C.F.R. § 164.514(b)(2).

Health care operations means any of the following activities of the covered entity to the extent that the activities are related to covered functions:

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;

(3) Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of §164.514(g) are met, if applicable;

(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and

(6) Business management and general administrative activities of the entity, including, but not limited to:

(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;

(ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.

(iii) Resolution of internal grievances;

(iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of §164.514, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity.
§ 164.501

Health plan means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

(1) Health plan includes the following, singly or in combination:

(i) A group health plan, as defined in this section.

(ii) A health insurance issuer, as defined in this section.

(iii) An HMO, as defined in this section.

(iv) Part A or Part B of the Medicare program under title XVIII of the Act.

(v) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, et seq.

(vi) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).

(vii) An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.

(viii) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(ix) The health care program for active military personnel under title 10 of the United States Code.

(x) The veterans health care program under 38 U.S.C. chapter 17.

(xi) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) (as defined in 10 U.S.C. 1072(4)).

(xii) The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, et seq.

(xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, et seq.

(xiv) An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, et seq.

(xv) The Medicare+Choice program under Part C of title XVIII of the Act, 42 U.S.C. 1395w–21 through 1395w–28.

(xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.

(xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg–91(a)(2)).

(2) *Health plan excludes:*

(i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg–91(c)(1); and

(ii) A government-funded program (other than one listed in paragraph (1)(i)–(xvi) of this definition):

(A) Whose principal purpose is other than providing, or paying the cost of, health care; or

(B) Whose principal activity is:

(1) The direct provision of health care to persons; or

(2) *The making of grants to fund the direct provision of health care to persons. § 160.103*

Indirect treatment relationship means a relationship between an individual and a health care provider in which:

(1) The health care provider delivers health care to the individual based on the orders of another health care provider; and

(2) *The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual. § 164.501*

Marketing means:

(1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, unless the communication is made:

(i) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits.

(ii) For treatment of the individual; or

(iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.

(2) An arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service. § 164.501

Payment means:

(1) The activities undertaken by:

(i) A health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or

(ii) A health care provider or health plan to obtain or provide reimbursement for the provision of health care; and

(2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to:

(i) Determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing;

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(v) Utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services; and

(vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:

(A) Name and address;

(B) Date of birth

(C) Social security number;

- (D) Payment history;
- (E) Account number; and
- (F) Name and address of the health care provider and/or health plan.

§ 164.501

Protected health information means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:

- (i) Transmitted by electronic media;
- (ii) Maintained in electronic media; or
- (iii) Transmitted or maintained in any other form or medium.

(2) Protected health information excludes individually identifiable health information in:

- (i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;
- (ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and
- (iii) Employment records held by a covered entity in its role as employer.

§ 160.103

Public health authority means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. *§ 164.501*

Required by law means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. *Required by law* includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits. *§ 164.501*

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. § 164.501

Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another. § 164.501

Use means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information. § 160.103

2. 42 CFR Part 2 definitions:

Alcohol abuse means the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user. 42 C.F.R. § 2.11

Drug abuse means the use of a psychoactive substance for other than medicinal purposes which impairs the physical, mental, emotional, or social well-being of the user. 42 C.F.R. § 2.11

Disclose or disclosure means a communication of patient identifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified. 42 C.F.R. § 2.11

Federal assistance. An alcohol abuse or drug abuse program is considered to be federally assisted if:

(1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (c)(2) of this section relating to the Veterans' Administration and the Armed Forces);

(2) It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to:

(i) Certification of provider status under the Medicare program;

(ii) Authorization to conduct methadone maintenance treatment (see 21 CFR 291.505); or

(iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of alcohol or drug abuse;

(3) It is supported by funds provided by any department or agency of the United States by being:

(i) A recipient of Federal financial assistance in any form, including financial assistance which does not directly pay for the alcohol or drug abuse diagnosis, treatment, or referral activities; or

(ii) Conducted by a State or local government unit which, through general or special revenue sharing or other forms of assistance, receives Federal funds which could be (but are not necessarily) spent for the alcohol or drug abuse program; or

(4) It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program. 42 C.F.R. § 2.12(a)

Patient identifying information means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the program. 42 C.F.R. § 2.11

Program director means:

(a) In the case of a program which is an individual, that individual:

(b) In the case of a program which is an organization, the individual designated as director, managing director, or otherwise vested with authority to act as chief executive of the organization. 42 C.F.R. § 2.11

Records means any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program. 42 C.F.R. § 2.11

Treatment means the management and care of a patient suffering from alcohol or drug abuse, a condition which is identified as having been caused by that abuse, or both, in order to reduce or eliminate the adverse effects upon the patient. 42 C.F.R. § 2.11

3. 22 M.R.S. §1711-C definitions:

Disclosure means the release, transfer of or provision of access to health care information in any manner obtained as a result of a professional health care relationship between the individual and the health care practitioner or facility to a person or entity other than the individual. 22 M.R.S. §1711-C(1)(B).

Health care information means information that directly identifies the individual and that relates to an individual's physical, mental or behavioral condition, personal or family medical history or medical treatment or the health care provided to that individual. "Health care information" does not include information that protects the anonymity of the individual by means of encryption or encoding of individual identifiers or information pertaining to or derived

from federally sponsored, authorized or regulated research governed by 21 Code of Federal Regulations, Parts 50 and 56 and 45 Code of Federal Regulations, Part 46, to the extent that such information is used in a manner that protects the identification of individuals. The Board of Directors of the Maine Health Data Organization shall adopt rules to define health care information that directly identifies an individual. Rules adopted pursuant to this paragraph are routine technical rules as defined in Title 5, chapter 375, subchapter II-A.

"*Health care information*" does not include information that is created or received by a member of the clergy or other person using spiritual means alone for healing as provided in Title 32, sections 2103 and 3270. 22 M.R.S. §1711-C(1)(E).

Health care practitioner means a person licensed by this State to provide or otherwise lawfully providing health care or a partnership or corporation made up of those persons or an officer, employee, agent or contractor of that person acting in the course and scope of employment, agency or contract related to or supportive of the provision of health care to individuals. 22 M.R.S. §1711-C(1)(F).

4. MHDO

22 MRS Section 8702. DEFINITIONS

2. Clinical data. "Clinical data" includes but is not limited to the data required to be submitted by providers and payors pursuant to sections 8708 and 8711.

4. Health care facility. "Health care facility" means a public or private, proprietary or not-for-profit entity or institution providing health services ... licensed by DHHS, but not pharmacies.

4-A. Health care practitioner. "Health care practitioner" has the meaning provided in Title 24, section 2502, subsection 1-A.

90-590 Chap 120: release of data

2. Definitions:

B. Clinical Data. "Clinical data" mean health care claims, hospital, non-hospital health care facility data, quality data, and all other data as described in 22 M.R.S.A. Secs. 8708, 8708-A, and 8711.

E. Disclosure. "Disclosure," with respect to clinical, financial, or restructuring data, means to communicate information to a person not already in possession of that information or to use information for a purpose not originally authorized. For example, to inform a person of the identity of a previously unnamed patient is to "disclose" clinical data not already in that person's possession with respect to the patient.

G. Financial Data. "Financial data" means information collected from data providers pursuant to Chapter 300 of the MHDO rules, *Uniform Reporting System for Hospital Financial Data*, that include, but are not limited to, costs of operation, revenues, assets, liabilities, fund balances, other income, rates, charges and units of services.

H. **Health Care Claims Data.** "Health care claims data" means information consisting of or derived directly from member eligibility, medical claims, pharmacy claims, and/or dental claims files submitted by health care claims processors pursuant to Chapter 243 of the MHDO's rules, *Uniform Reporting System for Health Care Claims Data Sets*. "Health care claims data" do not include analysis, reports, or studies containing information from health care claims data sets, if those analyses, reports, or studies have already been released in response to another request for information or as part of a general distribution of public information

J. **Health Care Facility.** "Health care facility" means a public or private, proprietary or not-for-profit entity or institution providing health services and which is licensed by State.

K. **Health Care Practitioner.** "Health care practitioner" means physicians and all others certified, registered or licensed in the healing arts, including but not limited to, nurses, podiatrists, optometrists, pharmacists, chiropractors, physical therapists, dentists, psychologists and physicians' assistants as defined in 24 M.R.S.A., chapter 21. "Health care practitioner" also includes licensed clinical social workers as defined in 32 M.R.S.A., chapter 83 and marriage and family therapists and professional counselors as defined in 32 M.R.S.A., chapter 119.

L. **Hospital Data.** "Hospital data" means information consisting of or derived directly from hospital inpatient, outpatient, emergency department, or any other derived data sets filed or maintained pursuant to Chapter 241 of the MHDO's rules, *Uniform Reporting System for Hospital Inpatient and Hospital Outpatient Data Sets*. "Hospital data" do not include analysis, reports, or studies containing information from hospital data sets, if those analyses, reports, or studies have already been released in response to another request for information or as part of a general distribution of public information by the MHDO.

N. **MHDO Records.**

1. "MHDO record" means any item of data stored in written, printed, graphic, or electronic form that is either:

(b) filed with the MHDO or its designee by a data provider in accordance with a requirement of statute, rule or MHDO order;

(d) contained in a final MHDO report, analysis, study, data compilation, decision, rule, or order;

2. "MHDO record" does not include any of the following:

(b) draft documents of any kind, including unsigned or incomplete memoranda, decisions, rules or other papers; nor

(c) reports studies, analyses, or data compilations that have not yet been reviewed for public release pursuant to section 9 or 10.

R. Privileged Medical Information. "Privileged medical information" means information other than hospital, non-hospital health care facility, or health care claims data that identify individual patients and that are derived from communications that:

1. were made for the purpose of diagnosis or treatment among a provider of health care, persons assisting the provider or patient, and a patient;
2. were made for the purpose of payment of health care services among a provider of health care, a health care claims processor, and a patient;
3. were not intended to be disclosed except to persons necessary to transmit or record the communication and persons participating in the diagnosis, treatment, or payment; and
4. have not been previously disclosed to the general public.

U. Release. To "release" data is to make it available for inspection and copying to persons other than the data provider.

90-590 MAINE HEALTH DATA ORGANIZATION, Chapter 125: HEALTH CARE INFORMATION THAT DIRECTLY IDENTIFIES AN INDIVIDUAL

C. Direct Identifier. "Direct identifier" means any information that discloses the identity of an individual. A case or code number used to create anonymous or encrypted medical data for research purposes is not a direct identifier

3. Identifying Information

Data elements determined to be direct identifiers of individuals include the following:

- A. Patient's Name;
- B. Names of Patient's Family Members;
- C. Insured's Name;
- D. Patient's or Insured's Address;
- E. Patient's or Insured's Telephone or FAX Numbers. Includes both home and work numbers;
- F. Patient Control Number. A unique alphanumeric number assigned by a health care provider to facilitate retrieval of individual financial records and posting of payment;
- G. Medical Record Number. A number assigned to the patient's medical/health record by the provider;
- H. Patient's Account Number. A unique number used by a health care provider or supplier to identify an individual's case records and for posting payment;

- I. Patient's or Insured's Social Security Number;
- J. Insured's Unique Health Insurance Identification Number;
- K. Insured's Unique Health Insurance Certificate Number;
- L. Patient's Medicare/Medicaid Health Insurance Identification Number;
- M. Patient's Federal Employees Compensation Act Number;
- N. Patient's or Insured's Credit Card Number;
- O. Patient's or Insured's Bank Account Number;
- P. Patient's or Insured's Operator's License Number;
- Q. Patient's or Insured's Vehicle Registration Number;
- R. Patient's or Insured's Vehicle License Plate Number;
- S. Patient's or Insured's Vehicle Identification Number;
- T. Patient's or Insured's Finger or Voice Prints;
- U. Patient's or Insured's Photographic Images;
- V. Patient's Pilot Medical Certificate Number;
- W. Patient's Maine Department of Corrections Inmate Identification Number;
- X. Patient's or Insured's Medical Device Identifiers and Serial Numbers; and
- Y. Any other unique number, characteristic, code or information that is a direct identifier.

Appendix G: Matrix of Laws for Protected Health Information

MATRIX OF LAWS FOR PHI

GENERAL HEALTH			
CATEGORY OF INFO.	<u>A</u> llowed <u>R</u> estricted <u>P</u> rohibited	Federal Law	Maine Law
Applicability		HIPAA rules include a security rule and a privacy rule for "covered entity (CE)." (45 C.F.R. § 164.302); (45 C.F.R. §§ 164.104, 164.500). CE is a "health plan" (individual or group plans that provide or pay medical care costs), health care clearinghouse (entities that standardize formatting (covers billing services, repricing companies, community health management information services, value-added networks if they perform the standardizing services), and every health care provider regardless of size AND who electronically transmits data). Covered entity is permitted, but not required to use and disclose PHI w/o consent to 1) individual; 2) TPO; 3) Opportunity to agree or object; 4) incident to otherwise permitted use and disclosure; 5) public interest and benefit activities; and 6) limited data set for research, public health or operations. When PHI is used or disclosed to entity that processes claims, data analysis, utilization review, and billing, the receiving entity is a "business associate" and requires a BA agreement (BAA). Expanded under ARRA/HITECH Act, to a BA with access to covered entity's PHI is bound by same HIPAA provisions as covered entity. (42 U.S.C. §17931(a)) Generally, whenever using, disclosing, or requesting PHI, a covered entity must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended use. (45 C.F.R. §164.502(b).	Health Care Facilities (22 M.R.S. §1711-C(1)(D)); Health Care Practitioners (22 M.R.S. §1711-C(1)(F)). Note: Maine's Privacy laws were written before federal privacy laws. Terms such as use or disclosure and release add ambiguity when trying to compare federal and state law. HIPAA law preempts state law, but allows states to have laws that provide more protection or laws that are termed "contrary" such as laws requiring provider to report public health types of info, or a law requiring <u>health plans</u> to report info for financial audits and for management.
Treatment, Payment, Operations	A	Entity with PHI can <u>disclose</u> to a receiving entity with a direct treatment relationship to patient; an entity with a direct treatment relationship can <u>use</u> PHI for treatment, payment, and operations purposes. (HIPAA / 45 CFR 164.502(a)(1)(ii)).	Health Care Facilities and Health Care Practitioners can disclose PHI to another Health Care Facility or Practitioner for diagnosis, treatment, or care of individuals (22 M.R.S.A. §1711-C(6)(A)); can disclose for payment (22 M.R.S.A. §1711-C(6)(L)).
Public Health	R	Can disclose minimum amount of PHI necessary to Public Health Authority authorized by law to collect PHI for the purpose of preventing or controlling disease, injury, disability (HIPAA / 45 CFR 164.512(b)(1)(i)); can rely on PHA's finding of minimum amount necessary (45 CFR 164.514(d)(3)(iii) (A)); no patient authorization is needed.	Can be disclosed to gov't in order to protect the public health and welfare when reporting is required or authorized by law (22 M.R.S. §1711-C(6)(E))

Research	R	Can disclose with IRB approval (45 CFR 164.512(i)(1)(i)) to prepare for research if PHI is not removed from covered entity (45 CFR 164.512(i)(1)(ii)); Limited data sets may be disclosed under data use agreements (45 CFR 164.514(e)).	Can disclose PHI to IRB-approved researchers, FDA clinical trials without patient authorization; researchers may not redisclose identifiable PHI (22 M.R.S. §1711-C(6)(G)). Other research requires patient authorization (22 M.R.S. §1711-C(3),(3-A), (3-B)); max duration of authorization: 30 months
Fundraising	R	45 CFR 164.501(6)(v) includes fundraising for benefit of covered entity as "operations" <u>use</u> ; <u>disclosure</u> of demographic info & dates of care is allowed to BA or institutionally related foundation for fundraising purposes (45 CFR §164.514(f)).	Law does not expressly address; therefore <u>disclosure</u> to persons other than patient for fundraising is prohibited; practitioners interpreted law to allow internal <u>use</u> for fundraising and for provider entities to directly solicit donations from patients but not from other persons; LWG opinion is that <u>internal fundraising use</u> doesn't constitute a <u>disclosure</u> .
Marketing	P	Covered entities can't use PHI for marketing without patient authorization (45 CFR 164.501, 508(a)3	Requires patient authorization (22 M.R.S. §1711-C(8))

SUBSTANCE ABUSE (Providers receiving federal assistance)

CATEGORY OF INFORMATION	A, R, P	Federal Law	Maine Law
Applicability		In addition to HIPAA, SA laws <u>apply only to drug or alcohol abuse (DAA) info</u> obtained by "federally assisted" DAA for diagnosis/treating/making referral DAA. 42 C.F.R. § 2.12(a)(ii); Federally assisted means: (1) conducted in whole or in part, directly or by contract or otherwise, by any dept/agency of US; (2) carried out under a license, certification, registration, or other authorization under Medicare; (3) methadone treatment; (4) dispense a controlled substance for DAA; (5) supported by US agency (i) by federal financial assistance not used directly pay for SAA diagnosis, treatment, or referral activities; or (ii) by State/local gov through general or special revenue sharing or other forms of assistance, receives Federal funds which could be (but are not necessarily) spent for the alcohol or drug abuse program; or (iii.) IRS allowing income tax deductions for contributions/ tax exempt status . 42 C.F.R. § 2.12(b)	Federal law governs (22 M.R.S.A. 1711-C(11)), but State licensing rules also apply; 14-118 CMR Chap 5, Section 15.2.2 and 18.4 (SA licensing rules)
Treatment, Payment, Operations	R	Only with patient <u>consent</u> (allowed: § 2.33; specific form of consent required: § 2.31) or for medical emergencies (42 CFR § 2.51)	22 M.R.S.A. §1711-C(11) states if there is another law, that law governs. So federal rule controls.
Public Health	R	Disclosure and use are allowed for gov't audit & evaluation of the program (42 C.F.R. § 2.53(a)); Auditors can disclose only that PHI necessary for audit or evaluation purposes (42 C.F.R. § 2.53(c)(4)).	22 M.R.S.A. §1711-C(11) states if there is another law, that law governs. So federal rule controls.
Research	R	Allowed if "required determination" (complex and lengthy process) is made under 42 C.F.R. § 2.52 by the substance abuse program director. Researchers may only disclose PHI back to program where PHI originated (42 C.F.R. § 2.52(b)).	22 M.R.S.A. §1711-C(11) states if there is another law, that law governs. So federal rule controls.
Fundraising	P	Rules are silent, given that intent of law is to prohibit use & disclosure except when specified (42 C.F.R. § 2.3(b)); LWG opinion is that fundraising use or disclosure would require patient consent.	22 M.R.S.A. §1711-C(11) states if there is another law, that law governs. So federal rule controls.

Marketing	P	Prohibited without patient authorization (42 U.S.C. §290ee-3, 42 U.S.C. §290dd-3; 42 C.F.R. Part 2)).	22 M.R.S.A. §1711-C(11) states if there is another law, that law governs. So federal rule controls.
HIV			
CATEGORY OF INFORMATION	A, R, P	Federal Law	Maine Law
Applicability		There is no specific federal HIV law. HIPAA rules for General Health apply.	Applies to any person or entity with HIV PHI (5 M.R.S. §19203)
Treatment, Payment, Operations	R	Entity with PHI can disclose to a receiving entity with a direct treatment relationship to patient; an entity with a direct treatment relationship can <u>use</u> PHI for treatment, payment, and operations purposes. (HIPAA / 45 CFR 164.502(a)(1)(ii)).	HIV test results can only be disclosed to entities designated by patient (5 M.R.S. §19203); health care providers may not disclose HIV PHI without patient authorization (statute 5 M.R.S. §19203-D(1)); doesn't preclude disclosure of other PHI (5 M.R.S. §19203-D(1)(B)). (Note: There are a few exceptions that permit disclosure in very limited situations)
Public Health	R	Can disclose minimum amount of PHI necessary to Public Health Authority authorized by law to collect PHI for the purpose of preventing or controlling disease, injury, disability (HIPAA / 45 CFR 164.512(b)(1)(i)); can rely on PHA's finding of minimum amount necessary (45 CFR 164.514(d)(3)(iii) (A)); no patient authorization is needed.	Notifiable diseases, which includes HIV, must be reported to DHHS (statute 22 M.R.S.A §822); and DHHS rule 10-144 C.M.R. Chapter 258(2)(I)) and some very limited exceptions that would permit disclosure such as abuse, organ & tissue donation, etc.
Research	R	Can disclose with IRB approval (45 CFR 164.512(i)(1)(i)) to prepare for research if PHI is not removed from covered entity (45 CFR 164.512(i)(1)(ii)); Limited data sets may be disclosed under data use agreements (45 CFR 164.514(e)).	Can disclose to researchers; researchers can't subsequently disclose (statute 5 M.R.S.A. §19203-D(3));
Fundraising	R	45 CFR 164.501(6)(v) includes fundraising for benefit of covered entity as "operations" <u>use</u> ; <u>disclosure</u> of demographic info & dates of care is allowed to BA or institutionally related foundation for fundraising purposes (45 CFR §164.514(f)).	5 M.R.S. §§ 19203 - 19203-D prohibit fundraising <u>use</u> & <u>disclosure</u> without patient authorization.
Marketing	P	Covered entities can't use PHI for marketing without patient authorization (45 CFR 164.501, 164.508(a)(3)).	Prohibited without patient authorization (Statute 5 M.R.S. §19203; 5 M.R.S.A. § 19203-D)

MHDO			
CATEGORY OF INFORMATION	A, R, P	Federal Law	State Law
Applicability		HIPAA laws do not apply because MHDO is not a covered entity. Maine's Attorney General's office has advised MHDO that they are a Public Health Authority, a term created in HIPAA that allows providers and hospitals to submit PHI to the PHA. (45 CFR 164.512(b) and 160.103).	MHDO is independent State agency (22 M.R.S. §8707(3)) governed by board; has rulemaking authority; most MHDO work done under provider agreements governed by MHDO rules. (90-590 CMR Chapter 120, §9 (D)). General notion is comprehensive health database to improve health of Maine people. Collects data on claims and finance (per rule, claims data) and in/outpatient, and specific quality indicators (per rule, clinical data). By statute, MHDO, under its vendor Onpoint, sends algorithm to payors who run their provider's data through algorithm and submit to Onpoint who encrypts further and sends to MHDO. (Rule, Chapter 243) In effect, double encryption. Must make info available to the public. In addition, entities must request data in writing per MHDO rules, and requests are approved by Board. Data provided may be unrestricted (receiver may further disclose) or restricted (no further disclosure allowed) depending on the type of data.
Treatment, Payment, Operations			Under Public Access (22 M.R.S.A.) Board must release information upon request and on web (quality measures) except privileged medical information and confidential information which can only be released if individual patients are not directly or indirectly identified through a reidentification process; additional protective protocols apply.
Public Health			There is an exception to the confidentiality law for Public Health Studies (including research) or when data is used only for verification or comparison of health data and Board finds that adequate protections exist.
Research			There is an exception to the confidentiality law for Public Health Studies (including research) or when data is used only for verification or comparison of health data and Board finds that adequate protections exist.
Fundraising			Not allowed
Marketing			Not allowed

HIN's HIE			
	A, R, P	Federal Law	State Law
CATEGORY OF INFORMATION			
Applicability		No specific federal law on HIEs. HIN / HIE is not a covered entity--it is a Business Associate under HIPAA and enters into BAAs, so from practical standpoint, is affected by HIPAA law.	SDHIE created by Executive Order. Confidentiality Statute covers SDHIE even though SDHIE not defined in law. (22 §1711-C.) No rulemaking authority. Practice is private agreements with providers govern exchange/release.
Treatment, Payment, Operations			May disclose w/o authorization if HIE has opt-out for general health information (HIE does have opt-out); based on this opt-out, may disclose for quality assurance, utilization review, billing and collection, regulatory or licensing authority; For MH and SA, HIE is opt-in. Only patients who opt-in for MH have their MH PHI disclosed. Currently, even if patient has opt-in for SA, HIN blocks SA PHI.
Public Health			May disclose to protect the public health and welfare when required or authorized by law
Research			By practice, they do not disclose for research
Fundraising			By practice, they do not disclose for fundraising.
Marketing			By practice, they do not disclose for marketing

Appendix H. MHDO State Statute on public access to data

Title 22 M.R.S. §8707. PUBLIC ACCESS TO DATA

The board shall adopt rules to provide for public access to data and to implement the requirements of this section. [1995, c. 653, Pt. A, §2 (NEW); 1995, c. 653, Pt. A, §7 (AFF).]

1. Public access; confidentiality. The board shall adopt rules making available to any person, upon request, information, except privileged medical information and confidential information, provided to the organization under this chapter as long as individual patients are not directly or indirectly identified through a reidentification process. The board shall adopt rules to protect the identity of certain health care practitioners, as it determines appropriate, except that the identity of practitioners performing abortions as defined in section 1596 must be designated as confidential and must be protected. Rules adopted pursuant to this subsection are major substantive rules as defined in Title 5, chapter 375, subchapter II-A.

[2001, c. 457, §14 (AMD) .]

2. Notice and comment period. The rules must establish criteria for determining whether information is confidential clinical data, confidential financial data or privileged medical information and adopt procedures to give affected health care providers and payors notice and opportunity to comment in response to requests for information that may be considered confidential or privileged.

[2003, c. 469, Pt. C, §27 (AMD) .]

3. Public health studies. The rules may allow exceptions to the confidentiality requirements only to the extent authorized in this subsection.

A. The board may approve access to identifying information for patients to the department and other researchers with established protocols that have been approved by the board for safeguarding confidential or privileged information. [2001, c. 457, §15 (AMD).]

B. The rules must ensure that:

- (1) Identifying information is used only to gain access to medical records and other medical information pertaining to public health;
- (2) Medical information about any patient identified by name is not obtained without the consent of that patient except when the information sought pertains only to verification or comparison of health data and the board finds that confidentiality can be adequately protected without patient consent;
- (3) Those persons conducting the research or investigation do not disclose medical information about any patient identified by name to any other person without that patient's consent;
- (4) Those persons gaining access to medical information about an identified patient use that information to the minimum extent necessary to accomplish the purposes of the research for which approval was granted; and
- (5) The protocol for any research is designed to preserve the confidentiality of all health care

information that can be associated with identified patients, to specify the manner in which contact is made with patients and to maintain public confidence in the protection of confidential information. [2001, c. 457, §15 (AMD).]

C. The board may not grant approval under this subsection if the board finds that the proposed identification of or contact with patients would violate any state or federal law or diminish the confidentiality of health care information or the public's confidence in the protection of that information in a manner that outweighs the expected benefit to the public of the proposed investigation. [2001, c. 457, §15 (AMD).]

[2001, c. 457, §15 (AMD) .]

4. Certain confidential information. The board may determine financial data submitted to the organization under section 8709 to be confidential information if the public disclosure of the data will directly result in the provider of the data being placed in a competitive economic disadvantage. This section may not be construed to relieve the provider of the data of the requirement to disclose such information to the organization in accordance with this chapter and rules adopted by the board.

[2011, c. 524, §4 (AMD) .]

5. Rules for release, publication and use of data. The rules must govern the release, publication and use of analyses, reports or compilations derived from the health data made available by the organization.

[1995, c. 653, Pt. A, §2 (NEW); 1995, c. 653, Pt. A, §7 (AFF) .]

SECTION HISTORY

1995, c. 653, §A2 (NEW). 1995, c. 653, §A7 (AFF). 1999, c. 353, §§12,13 (AMD). 2001, c. 457, §§14,15 (AMD). 2003, c. 469, §C27 (AMD). 2007, c. 466, Pt. A, §44 (AMD). 2011, c. 524, §4 (AMD).

22 §8708. CLINICAL DATA

Clinical data must be filed, stored and managed as follows. [1995, c. 653, Pt. A, §2 (NEW); 1995, c. 653, Pt. A, §7 (AFF).]

1. Information required. Pursuant to rules adopted by the board for form, medium, content and time for filing, each health care facility shall file with the organization the following information:

A. [1999, c. 353, §14 (RP).]

B. A completed uniform hospital discharge data set, or comparable information, for each patient discharged from the facility after June 30, 1983 and for each hospital outpatient service occurring after June 30, 1996; and [1999, c. 353, §14 (AMD).]

C. In addition to any other requirements applicable to specific categories of health care facilities, the organization may require the filing of data as set forth in this chapter or in rules adopted pursuant to this chapter. [1999, c. 353, §14 (AMD).]

[1999, c. 353, §14 (AMD) .]

2. Additional information on ambulatory services and surgery. Pursuant to rules adopted by the board for form, medium, content and time for filing, each provider shall file with the organization a

completed data set, comparable to data filed by health care facilities under subsection 1, paragraph B. This subsection may not be construed to require duplication of information required to be filed under subsection 1.

[2001, c. 457, §16 (AMD) .]

3. More than one licensed health care facility or location. When more than one licensed health care facility is operated by the reporting organization, the information required by this chapter must be reported for each health care facility separately. When a provider of health care operates in more than one location, the organization may require that information be reported separately for each location.

[1995, c. 653, Pt. A, §2 (NEW); 1995, c. 653, Pt. A, §7 (AFF) .]

4. Data lists.

[2001, c. 457, §17 (RP) .]

5. Medical record abstract data. In addition to the information required to be filed under subsections 1 and 2 and pursuant to rules adopted by the organization for form, medium, content and time of filing, each health care facility shall file with the organization such medical record abstract data as the organization may require.

[1995, c. 653, Pt. A, §2 (NEW); 1995, c. 653, Pt. A, §7 (AFF) .]

6. Merged data. The board may require the discharge data submitted pursuant to subsection 1 and any medical record abstract data required pursuant to subsection 5 to be merged with associated billing data.

[1995, c. 653, Pt. A, §2 (NEW); 1995, c. 653, Pt. A, §7 (AFF) .]

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.

[2007, c. 136, §6 (AMD) .]

7. 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.

[1995, c. 653, Pt. A, §2 (NEW); 1995, c. 653, Pt. A, §7 (AFF) .]

SECTION HISTORY

1995, c. 653, §A2 (NEW). 1995, c. 653, §A7 (AFF). 1997, c. 525, §4 (AMD). 1999, c. 353, §14 (AMD). 2001, c. 457, §§16-18 (AMD). 2007, c. 136, §6 (AMD).

22 §8708-A. QUALITY DATA

The board shall adopt rules regarding the collection of quality data. The board shall work with the

Maine Quality Forum and the Maine Quality Forum Advisory Council established in Title 24-A, chapter 87, subchapter 2 to develop the rules. The rules must be based on the quality measures adopted by the Maine Quality Forum pursuant to Title 24-A, section 6951, subsection 2. The rules must specify the content, form, medium and frequency of quality data to be submitted to the organization. In the collection of quality data, the organization must minimize duplication of effort, minimize the burden on those required to provide data and focus on data that may be retrieved in electronic format from within a health care practitioner's office or health care facility. As specified by the rules, health care practitioners and health care facilities shall submit quality data to the organization. Rules adopted pursuant to this section are major substantive rules as defined in Title 5, chapter 375, subchapter 2-A. [2003, c. 469, Pt. C, §28 (NEW).]

Appendix I. MHDO rule on release of data

90-590 MAINE HEALTH DATA ORGANIZATION

Chapter 120: RELEASE OF DATA TO THE PUBLIC

SUMMARY: This chapter provides for the manner and extent to which data submitted to or assembled by the MHDO or its predecessor agencies will be made available to the public. The rule defines the scope of the exceptions to the Freedom of Access Law that is provided in the Maine Health Data Organization statute. The rule also establishes procedures for determining whether data are confidential or privileged and for protecting filed data until that decision is made.

1. Applicability

This rule governs disclosure to the public of data in the possession of the Maine Health Data Organization or its designee. Only data that are physically recorded or stored in written, printed, graphic, or electronic form, as opposed to the individual knowledge of Board or staff members, are covered by this rule. The coverage of all such data in this rule shall not be construed as an MHDO determination that all recorded or stored data within its offices or those of its designee are "public records" within the meaning of 1 M.R.S.A. Sec. 402(3) (1996).

2. Definitions

- A. **Carrier.** "Carrier" means an insurance company licensed in accordance with 24-A M.R.S.A., including a health maintenance organization, a multiple employer welfare arrangement licensed pursuant to Title 24-A, chapter 81, a preferred provider organization, a fraternal benefit society, or a nonprofit hospital or medical service organization or health plan licensed pursuant to 24 M.R.S.A. An employer exempted from the applicability of 24-A M.R.S.A., chapter 56-A under the federal Employee Retirement Income Security Act of 1974, 29 United States Code, Sections 1001 to 1461 (1988) is not considered a carrier.
- B. **Clinical Data.** "Clinical data" mean health care claims, hospital, non-hospital health care facility data, quality data, and all other data as described in 22 M.R.S.A. Secs. 8708, 8708-A, and 8711.

C. **Confidential Data.** "Confidential data" mean "Confidential Restructuring Data," "Confidential Agency Data", "Confidential Clinical Data," or "Confidential Financial Data," as defined below:

1. "Confidential Restructuring Data" mean any information filed by a data provider in connection with its corporate plan or reorganization that contains either a trade secret or contract information:
 - (a) that have not yet been revealed to persons other than:
 - (i) employees, agents, or attorneys of the data provider;
 - (ii) other persons or entities with which the data provider is engaged in a joint venture or other commercial action in concert;
 - (iii) other persons or entities with which the data provider is actively negotiating for the purchase or sale of goods or services;
 - (iv) other persons or entities with which the data provider is jointly participating in an effort to obtain financing; and
 - (v) other persons or entities to which the data provider has applied for financing;
 - (b) that would, if revealed, substantially and adversely affect the ability of the data provider, its affiliated interests or the other persons or entities with which the data provider is engaging in a joint venture or commercial action to compete with other entities offering or proposing to offer the same goods and services in the same market; or, that would, if revealed, substantially and adversely affect the ability of the data provider or its affiliated interest to obtain financing on reasonable terms in competition with others seeking similar types of capital; or
 - (c) that could lawfully be concealed under applicable laws governing financial transactions.
2. "Confidential Agency Data" are data collected or produced by the MHDO that:
 - (a) have not been revealed to the general public;

- (b) can be withheld from public access without violation of the Freedom of Access Law, 1 M.R.S.A. Sec. 400 *et seq.*; and
 - (c) should not, in the opinion of the Executive Director, be released.
- 3. "Confidential Clinical Data" or "Confidential Financial Data" are data provided to the MHDO that:
 - (a) have not been revealed to the general public; and
 - (b) will directly result in the data provider being placed in a competitive economic disadvantage.
- D. **Data Provider.** A "data provider" provides data to the MHDO pursuant to 22 M.R.S.A. Secs. 8708, 8708-A, 8709, 8710 or 8711 and is a health care facility, health care practitioner, or health care claims processor.
- E. **Disclosure.** "Disclosure," with respect to clinical, financial, or restructuring data, means to communicate information to a person not already in possession of that information or to use information for a purpose not originally authorized. For example, to inform a person of the identity of a previously unnamed patient is to "disclose" clinical data not already in that person's possession with respect to the patient.
- F. **Executive Director.** "Executive Director" means the Executive Director of the MHDO or his/her successors.
- G. **Financial Data.** "Financial data" means information collected from data providers pursuant to Chapter 300 of the MHDO rules, *Uniform Reporting System for Hospital Financial Data*, that include, but are not limited to, costs of operation, revenues, assets, liabilities, fund balances, other income, rates, charges and units of services.
- H. **Health Care Claims Data.** "Health care claims data" means information consisting of or derived directly from member eligibility, medical claims, pharmacy claims, and/or dental claims files submitted by health care claims processors pursuant to Chapter 243 of the MHDO's rules, *Uniform Reporting System for Health Care Claims Data Sets*. "Health care claims data" do not include analysis, reports, or studies containing information from health care claims data sets, if those analyses, reports, or studies have already been released in response to another request for information or as part of a general distribution of public information by the MHDO.

- I. **Health Care Claims Processor.** "Health care claims processor" means a third-party payer, third-party administrator, Medicare health plan sponsor, or pharmacy benefits manager.

- J. **Health Care Facility.** "Health care facility" means a public or private, proprietary or not-for-profit entity or institution providing health services including, but not limited to a radiological facility licensed under 22 M.R.S.A., chapter 160, a health care facility licensed under 22 M.R.S.A., chapter 405 or certified, an independent radiological service center, a federally qualified health center certified by the United States Department of Health and Human Services, Health Resources and Services Administration, a rural health clinic, or a rehabilitation agency certified, or otherwise approved by the Division of Licensing and Regulatory Services within the Department of Health and Human Services, a home health care provider licensed under 22 M.R.S.A., chapter 419, a residential care facility licensed under 22 M.R.S.A., chapter 1663, a hospice provider licensed under 22 M.R.S.A., chapter 1681, a retail store drug outlet licensed under 32 M.R.S.A., chapter 117, a state institution as defined under 34-B M.R.S.A., chapter 1 and a mental health facility licensed under 34-B M.R.S.A., chapter 1.

- K. **Health Care Practitioner.** "Health care practitioner" means physicians and all others certified, registered or licensed in the healing arts, including but not limited to, nurses, podiatrists, optometrists, pharmacists, chiropractors, physical therapists, dentists, psychologists and physicians' assistants as defined in 24 M.R.S.A., chapter 21. "Health care practitioner" also includes licensed clinical social workers as defined in 32 M.R.S.A., chapter 83 and marriage and family therapists and professional counselors as defined in 32 M.R.S.A., chapter 119.

- L. **Hospital Data.** "Hospital data" means information consisting of or derived directly from hospital inpatient, outpatient, emergency department, or any other derived data sets filed or maintained pursuant to Chapter 241 of the MHDO's rules, *Uniform Reporting System for Hospital Inpatient and Hospital Outpatient Data Sets*. "Hospital data" do not include analysis, reports, or studies containing information from hospital data sets, if those analyses, reports, or studies have already been released in response to another request for information or as part of a general distribution of public information by the MHDO.

- L-1. **Medicare Health Plan Sponsor.** "Medicare health plan sponsor" means a health insurance carrier or other private company authorized by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services to administer Medicare Part C and Part D benefits under a health plan or prescription drug plan.

- M. **MHDO.** “MHDO” means the Maine Health Data Organization or its predecessor agencies.
- N. **MHDO Records.**
1. “MHDO record” means any item of data stored in written, printed, graphic, or electronic form that is either:
 - (a) contained within the official agency record of an MHDO rulemaking proceeding;
 - (b) filed with the MHDO or its designee by a data provider in accordance with a requirement of statute, rule or MHDO order;
 - (c) contained in the minutes of MHDO meetings; or
 - (d) contained in a final MHDO report, analysis, study, data compilation, decision, rule, or order;
 2. “MHDO record” does not include any of the following:
 - (a) the contents of files maintained by the MHDO's lawyers, or any material prepared in anticipation of litigation;
 - (b) draft documents of any kind, including unsigned or incomplete memoranda, decisions, rules or other papers; nor
 - (c) reports studies, analyses, or data compilations that have not yet been reviewed for public release pursuant to section 9 or 10.
- O. **M.R.S.A.** “M.R.S.A.” means Maine Revised Statutes Annotated.
- P. **Non-Hospital Health Care Facility Data.** “Non-hospital health care facility data” means information or data consisting of or derived directly from data sets filed or maintained pursuant to Chapter 245 of the MHDO’s rules, *Uniform Reporting System for Non-Hospital Ambulatory Service Data Sets*. “Non-hospital health care facility data” do not include analysis, reports, or studies containing information from non-hospital health care facility data sets, if those analyses, reports, or studies have already been released in response to another request for information or as part of a general distribution of public information by the MHDO.

- P-1. **Pharmacy Benefits Manager.** "Pharmacy benefits manager" means an entity that performs pharmacy benefits management as defined by 22 M.R.S.A., § 2699.
- Q. **Plan Sponsor.** "Plan sponsor" means any person, other than an insurer, who establishes or maintains a plan covering residents of the State of Maine, including, but not limited to, plans established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, or the association, committee, joint board of trustees or other similar group of representatives of the parties that establish or maintain the plan.
- Q-1. **Prescriber Data.** "Prescriber data" means information or data collected from data providers pursuant to Chapter 280 of the MHDO's rules, *Filing Requirements for Prescribers Seeking Confidentiality Requirements*, that include, but are not limited to, prescriber names, addresses, Maine license or certificate numbers, Drug Enforcement Authority registration numbers, and National Provider Identification numbers.
- R. **Privileged Medical Information.** "Privileged medical information" means information other than hospital, non-hospital health care facility, or health care claims data that identify individual patients and that are derived from communications that:
1. were made for the purpose of diagnosis or treatment among a provider of health care, persons assisting the provider or patient, and a patient;
 2. were made for the purpose of payment of health care services among a provider of health care, a health care claims processor, and a patient;
 3. were not intended to be disclosed except to persons necessary to transmit or record the communication and persons participating in the diagnosis, treatment, or payment; and
 4. have not been previously disclosed to the general public.
- S. **Protected Information.** "Protected information" means information that is subject to a protective order that was issued by a court and is binding on the MHDO or that was issued by the MHDO, either as part of an adjudicatory proceeding or as a general order pursuant to section 12 of this Chapter.

- T. **Quality Data.** "Quality data" means information consisting of or derived directly from data providers pursuant to Chapter 270 of the MHDO's rules, *Uniform Reporting System for Quality Data Sets*. "Quality data" do not include analysis, reports, or studies if those analyses, reports, or studies have already been released as part of a general distribution of public information by the MHDO.
- U. **Release.** To "release" data is to make it available for inspection and copying to persons other than the data provider.
- V. **Restructuring Data.** "Restructuring data" means information collected from data providers pursuant to Chapter 630 of the MHDO rules, *Uniform System for Reporting Baseline Information and Restructuring Occurrences for Maine Hospitals and Parent Entities*, that include, but are not limited to, organizational structure, location of separate health service delivery sites or treatment centers, acquisitions, consolidations, or mergers.
- W. **Staff Delegate.** "Staff delegate" means a member of the MHDO staff to whom the Executive Director delegates specific responsibilities under this Chapter.
- X. **Third-Party Administrator.** "Third-party administrator" means any person licensed by the Maine Bureau of Insurance under 24-A M.R.S.A., chapter 18 who, on behalf of a plan sponsor, health care service plan, nonprofit hospital or medical service organization, health maintenance organization or insurer, receives or collects charges, contributions or premiums for, or adjusts or settles claims on residents of this State.
- Y. **Third-Party Payer.** "Third-party payer" means a state agency that pays for health care services or a health insurer, carrier, including a carrier that provides only administrative services for plan sponsors, nonprofit hospital, medical services organization, or managed care organization licensed in the State. "Third-party payer" does not include carriers licensed to issue limited benefit health policies or accident, specified disease, vision, disability, long-term care or nursing home care policies.

3. **Public Access to Data**

- A. **MHDO Records Not Otherwise Restricted.** Except as otherwise provided in this section, all MHDO records shall be released to any person, in accordance with sections 4 and 5, below.
- B. **Clinical Data.** MHDO records, files, reports, tables or any other information consisting of or compiled from clinical data shall be released, but only after the review and modification procedures set forth in section 9 have been

undertaken. Computations, reports, or tables containing clinical data may be released without review, if the data have previously been designated as public.

- C. **Financial or Restructuring Data.** MHDO files, reports, tables or any other information consisting of or compiled from financial or restructuring data shall be released in accordance with the provisions set forth in section 10. Computations, reports, or tables containing financial or restructuring data may be released without review, if the data have previously been designated as public.
- D. **Data Claimed to be Confidential or Privileged.** Those parts of MHDO records that have been properly claimed to contain confidential data or privileged medical information pursuant to section 6 shall not be released unless the Executive Director or a staff delegate determines, pursuant to section 7 or section 8, that the requested data or medical information are not confidential or privileged.
- E. **MHDO Documents Containing Confidential, Privileged, or Protected Data.** MHDO documents labeled in accordance with subsection 11(A), shall not be released, until the confidential, privileged, or protected data have been removed or obliterated.
- F. **Data Subject to Protective Order.** Those parts of MHDO records that are subject to a protective order and are properly labeled as protected shall not be released except to the extent that the order may allow.
- G. **Information Other than MHDO Records.** Information in the MHDO's possession that does not constitute or form part of a MHDO record may be released after a request made in accordance with section 4, only if the Executive Director or a staff delegate finds that review under subsection 11(C) is not required and either:
 - 1. that the information is a "public record" within the meaning of 1 M.R.S.A. Sec. 402 (3); or
 - 2. that the information is not a "public record" but that its disclosure:
 - (a) will not infringe upon confidential, privileged, or protected status provided elsewhere in this Chapter; and
 - (b) will be appropriate and reasonable as determined by the Executive Director or staff delegate.

- H. **Prescriber Data.** MHDO files, reports, tables, or any other information consisting of or compiled from prescriber data shall be released, but must not contain any data as identified in section 9(A)(4).

4. **Request for Data**

- A. **Request for Data.** Each request for data shall be in writing and shall state with specificity: the MHDO data or other information sought; the identity, including ownership, of the requesting party; whether or not an internal review board is to be utilized; the purpose(s) for which it will be used; and the media on which the data are to be delivered. If the requesting party intends to display on the Internet any of the data sought, the request for such data must so specify. Any request that does not contain sufficient detail to enable the MHDO's staff to locate the desired data with a reasonable expenditure of time and effort may be rejected without being granted or denied. When clinical data requests contain data elements as set forth in subsections 9(A)(2), (3), and (4) of this Chapter, the request shall also set forth:

1. the ultimate recipient or user of the data;
2. any facts bearing on the willingness and ability of the requesting party and ultimate recipient or user of the data to comply with subsection 9 (B)(2)(b) of this Chapter; and
3. the term during which the research will be conducted or the data will be utilized.

In order to ensure that the standards and conditions set forth in section 9 and 10 are met, the Executive Director or staff delegate may request additional information from the requesting party.

- B. **Initial Action on Request.** Upon the filing of a request, the Executive Director or a staff delegate shall determine whether any portions of the information requested must be reviewed under sections 7, 8, 9, or 10 below, or must be modified under subsection 3(E), above. Within thirty business days of the filing of the request, the Executive Director or a staff delegate shall:

1. release to the requesting party pursuant to section 5 all information not subject to review under sections 7, 8, 9, and 10, and not withheld from release pursuant to subsections 3(E), (F), and (G);
2. issue a written denial with respect to any information withheld pursuant to subsections 3(E), (F), or (G); and

3. issue a written, temporary denial with respect to any requested information subject to sections 7, 8, 9, or 10, including an explanation to the requesting party that further steps are required to comply with statutory restrictions on the release of the information or to seek review of an agency determination of confidentiality.
- C. **Reconsideration of Initial Action.** Any requesting party who has not been provided an opportunity to be heard on the reasons stated in a written denial may request reconsideration within 5 days of the service of the denial. All facts and arguments in support of the motion shall be recited therein. If the Executive Director determines the written submissions do not provide a sufficient basis for a decision, the Executive Director may convene a hearing pursuant to the Maine Administrative Procedures Act.

5. Release of Information and Data

- A. **Inspection and Copying of Existing Documents.** Inspection and copying shall be conducted:

1. at the offices in which the information released is made available; and
2. in a manner that assures that the copied material is not damaged.

The Executive Director or a staff delegate may require that copying be conducted by MHDO staff.

- B. **Copying Costs.** Reasonable costs of copying shall be paid by the requesting party. Upon request, MHDO staff shall provide estimates of cost in advance of copying. The estimates shall be based upon the applicable fees listed in Chapter 50 of the MHDO's rules.

- C. **Translation, Compilation, Reconfiguration, and Modification**

1. When information must be translated from one medium to another, compiled from several sources, reconfigured, or modified to avoid disclosure of information that must under this Chapter be withheld, the costs of all such operations shall be charged to the requesting party. Such charges must be paid before the requested information is delivered.
2. Notwithstanding the thirty business day period provided in subsection 4(B), when the operations described above in subsection 5(C)(1) are required to fulfill a request, such operations and subsequent inspection

may be scheduled to occur at such time as will not delay or inconvenience the regular activities of the MHDO staff.

D. **Notice of Release**

Whenever financial or restructuring data pertaining to a specific data provider are released, the MHDO shall notify the filing party.

6. **Claims of Confidentiality or Privilege**

A. **Responsibility of Data Provider**

1. **At Time of Submission.** Whenever a data provider claims that data are confidential or privileged within the meanings established in section 2, it shall clearly label each page (or, in the case of electronically stored data, each subdivision of similar size) to which the claim applies as "Confidential" or "Privileged," before submitting the data to MHDO. Each submission that includes portions labeled as confidential or privileged shall be accompanied by a covering letter or report that sets forth the basis for each claim of confidentiality or privilege.
2. **Subsequent to Submission.** When a data provider discovers or concludes, after the submission of data, that they are confidential or privileged and should have been so labeled, it may submit a request that such data be labeled by the MHDO or that the MHDO substitute a labeled copy of the data for the original submission. Any such request shall be accompanied by a letter or report of the basis for the claim of confidentiality or privilege. If the data provider agrees to assume all costs associated with any processing or other data filing, tabulation, recording, or management activities that must be repeated in order to accomplish, or as a consequence of, the subsequent labeling of data, the MHDO will cause the data designated in the request to be labeled as confidential or privileged, or will substitute labeled duplicates and return the original materials. Thereafter, such subsequently labeled material will be treated in the same manner as data claimed to be confidential or privileged pursuant to subsection 6(A)(1), above. Nothing in the subsection, however, shall require the MHDO to retrieve copies of unlabeled data that have been distributed prior to completion of the process of subsequent labeling set forth in this paragraph. The MHDO shall conduct such labeling activities within such time and in such manner as will not disrupt or delay the completion of its other administrative responsibilities.

- B. **MHDO Claims.** Whenever the Executive Director or a staff delegate considers data that is an MHDO record to be confidential agency data, such data shall be labeled in the same manner provided for data providers in subsection 6(A). This section shall not be construed to require the MHDO or the staff to comply with subsection 6(A) with respect to confidential agency information that is not an MHDO record.
- C. **Disclosure Prohibited.** No data that are properly claimed to be privileged or confidential as provided in this section shall be released, unless the claim is denied after a review under section 7 or 8.

7. Review of Data Claimed by a Data Provider to be Confidential or Privileged

When a request for data includes material labeled by a data provider under section 6, the procedures set forth in this section shall apply.

- A. **Notification.** The data provider or providers that submitted the labeled data shall be notified of the request.
- B. **Written Support for Confidential or Privileged Designation.** Within ten (10) days of notification, the data provider(s) may submit written memoranda of all facts and arguments that support the claim that the data requested should be found to be confidential or privileged. Copies of such memoranda shall be served on the requesting party.

NOTE: For purposes of computing this ten-day period, MHDO will consider notification to mean service of the notification, in a manner and with the same effect as service under the Maine Rules of Civil Procedure.

- C. **Written Opposition from Requesting Party.** Within ten (10) days of the service of the memoranda provided for in subsection 7(B), any opposing memorandum from the requesting party shall be filed.
- D. **Burden of Proof.** In reviews under this section, the burden of proof shall rest on the data provider(s) contending that information should not be released. Therefore, if the submissions under subsection 7(B) fail to establish that the data under review are privileged or confidential, the Executive Director or a staff delegate may issue a decision releasing the data without further hearing, subject to the restriction of subsection 7(G).
- E. **Requirements for Hearing.** No hearing will be held under this section unless, after review of the memoranda, the Executive Director determines that the memoranda filed do not provide a sufficient basis for a decision, in which case

the Executive Director may convene a hearing pursuant to the Maine Administrative Procedure Act.

- F. **Review Period for Release.** A decision on whether to release data shall be made within thirty days (30) of the notification given under subsection 7(A).
- G. **Effective Release Date.** No decision to release data that have been labeled under section 6 shall take effect less than five days after service of the decision on the data provider.
- H. **Modification of Time Periods.** The time periods provided in this section may be modified in particular instances to accommodate the needs of the requesting party or to assure that decisions under this section do not interfere with the MHDO's performance of its primary statutory duties.
- I. **Labeling of Data Deemed to be Public.** Once particular items of data have been found not to be privileged or confidential pursuant to this section, a notation to that effect may be made on the affected documents. Thereafter, such items will be treated for purposes of this Chapter as if they were not labeled confidential or privileged. The necessary notation may be accomplished by labeling such items as "public."

8. Review of Data Claimed to be Confidential Agency Data

When a request for data includes material labeled as confidential agency data by the Executive Director or a staff delegate under subsection 6 (B), the procedures set forth in this section shall apply.

- A. **Notification.** The requesting party shall be notified that portions of its request are claimed to be confidential by the MHDO, and of the basis for that claim.
- B. **Written Support.** The requesting party may submit written memoranda of all facts and arguments that support the claim that the data requested should not be treated as confidential, within five days of the notification given pursuant to subsection (A).
- C. **Response to Requesting Party.** If the Executive Director or a staff delegate requests further comment or a response to the requesting party's memoranda from members of the MHDO staff, such comment or response shall be served on the requesting party.
- D. **Requirements for Hearing.** No hearing will be held under this section unless, after review of the memoranda, the Executive Director determines that the memoranda filed does not provide a sufficient basis for a decision.

- E. **Review Period for Release.** A decision on whether to release information shall be made within twenty (20) days of the notification given under subsection 7(A).
- F. **Modification of Time Periods.** The time periods provided in this section may be modified in particular instances to accommodate the needs of the requesting party or to assure that decisions under this section do not interfere with the MHDO's performance of its primary statutory duties.
- G. **Labeling of Data Deemed to be Public.** Once particular items of data have been found not to be privileged or confidential pursuant to this section, a notation to that effect may be made on the affected documents. Thereafter, such items will be treated for purposes of this Chapter as if they were not labeled confidential or privileged. The necessary notation may be accomplished by labeling such items as "public."

9. **Review of Requests for Clinical Data**

Clinical data will be released after they have been reviewed in accordance with this section.

- A. The Executive Director or a staff delegate shall compare the clinical data request with the following standards to establish the scope and extent of the request.
 - 1. In accordance with section 3 of Chapter 125 of the MHDO's rules data that directly identify patients, shall not be included in data that are released, unless an exception has been specifically authorized in accordance with subsection 9(D). Data elements that are direct identifiers of individuals under section 3 of Chapter 125 shall be released only in an encrypted form that cannot be used to identify individuals, although it may permit distinctions to be made among unidentifiable individuals. Any data element that is listed under section 3 of Chapter 125 must also be listed in subsection 9(A)(2)(g) to be released in an encrypted format.
 - 2. The following data elements shall be considered to have a possibility of indirectly identifying patients if they show for any individual health record any of the following information and may only be released in accordance with subsection 9(B)(2), unless an exception has been specifically authorized in accordance with section 9(D):
 - (a) date of birth, unless converted to age;

- (b) hospital inpatient admission date or hospital inpatient discharge date, unless each is converted to length of stay plus calendar quarter and year;
 - (c) hospital inpatient procedure date, unless converted to the number of elapsed days between admission and procedure date;
 - (d) date of procedure or service, unless converted to calendar quarter and year;
 - (e) race;
 - (f) when the place of residence is coded at a level that includes populations of 20,000 persons or less, except to the extent that the MHDO may, by order, approve the use of health planning, regulatory, or research areas containing smaller populations;
 - (g) medical record number, patient control number, plan specific contract number, member identification code, or patient social security number, in an encrypted form that cannot be used to identify individuals; or
 - (h) insured group or policy number if the total number of individuals in the group is 50 or greater, or, if less, data associated with other elements listed in this sub-section have been removed prior to release to prevent indirect identification.
3. Data elements related to health care facility or practitioner charges (total charges, line item charges, charge amount) for services rendered shall only be released at an aggregate level that will not allow a charge/paid ratio to be computed for each type of service rendered for any individual health care claims processor, health care facility, or health care practitioner. Requesting parties are prohibited from simultaneously arraying and/or displaying data elements related to payments for specific health care services by individual health care claims processors and health care facilities or practitioners. The MHDO may create public reports or tables arrayed in this manner when all applicable health care facility and practitioner claims for a specific service have been aggregated to produce the total price paid.
4. Any data that directly identifies or would lead to the indirect identification of practitioners performing abortions as defined by 22 M.R.S.A. § 1596, a practitioner's tax identification number, or a

practitioner's Drug Enforcement Administration registration number are deemed to be confidential and shall not be released.

B. Release of Clinical Data

1. Upon completion of the review requirements of Section 12, data that meet the standards of subsection 9(A)(1) and contain none of the combinations of data described in subsections 9(A)(2)(3) and (4) shall be released without further review.
2. Except to the extent the data are modified by subsection 9(D), when clinical data meet the standards of subsection 9(A)(1) but contain data elements as described in subsections 9(A)(2), (3), and (4), the following procedure will be employed:
 - (a) If the Executive Director or a staff delegate finds, on the basis of information received pursuant to section 4:
 - (i) that the requesting party is seeking the requested clinical data solely for research or statistical purposes;
 - (ii) that the requesting party is seeking only the clinical data that is necessary to fulfill the specific requirements of the data request;
 - (iii) that the requesting party has agreed in a writing filed with the MHDO to adhere to the conditions set forth in subsection 9(B)(2)(b); and
 - (iv) that the requesting party has demonstrated that it can and will faithfully adhere to such conditions and has established procedures to insure such adherence by both it and its employees;

then the MHDO shall initiate the process to release the data that fall within the scope of subsections 9(A)(2), (3), and (4), upon the conditions specified in subsection 9(B)(2)(b). The release of the clinical data shall conform to the external review provisions described in section 12.

- (b) Any person to whom clinical data containing elements as set forth in subsections 9(A)(2), (3), and (4) are released shall comply with the conditions in this subsection and shall agree to so comply in writing before receiving any such data.

- (i) The data provided will be used by the requesting party and its employees only for research and statistical purposes and only for those purposes specified in the data request, as approved by the MHDO.
- (ii) The MHDO shall retain all ownership rights to the data. The requesting party shall have no right, title, or interest to any of the data provided by the MHDO.
- (iii) The requesting party shall name an individual as custodian of the data to be responsible for the observance of all conditions of use and for establishment and maintenance of security arrangements to prevent unauthorized use.
- (iv) The requesting party shall not release, furnish, disclose, publish or otherwise disseminate the data released to it by the MHDO under this subsection, to any person, except an employee of the requesting party who has agreed in writing to comply with all of the conditions of this paragraph and is subject to such supervision by the requesting party as is necessary to insure such compliance. Nothing in this subsection, however, shall prevent the requesting party from releasing or disclosing those portions of the data that do not include any of the data elements found in subsections 9(A)(2)(3) and (4).
- (v) The requesting party shall make only such additional copies of the data as are required in the conduct of the research and shall retain only one copy of the data after the term of the research as specified in the request, or as modified by the MHDO in approving the request, concludes. All other copies shall be destroyed or returned to the MHDO at the conclusion of the term of the research.
- (vi) The requesting party shall not use the data provided in any way, or allow such data to be used in any way, for purposes of identifying individuals or taking legal, administrative or other actions against individuals, nor shall the requesting party make contact with, or assist others in making contact with, any individuals who may be indirectly identified in the data provided.

- (vii) The requesting party agrees that the data may be retained only for the period of time necessary to fulfill the requirements of the data request. The requesting party shall return the data within 30 days of the scheduled completion date of the project or shall destroy the data, so certifying by submitting a written notice to the MHDO.

- (viii) Except as provided in subsection 9 (B)(2)(b)(ix) the requesting party shall provide the MHDO with a copy of any manuscript, report, or web site universal resource locator (URL) intended for public dissemination that contain data provided under subsection 9(A) at least twenty days prior to their release unless the manuscript, report, or web site is being furnished only to:
 - a. the requesting party's employees or its other investigators who have agreed with the provisions of this paragraph; or
 - b. the MHDO.

In the event the MHDO determines that the report may lead to direct or indirect identification of individuals or the determination of a charge/paid ratio, the requesting party shall modify the report prior to its release to protect against such occurrence.

When multiple reports of a similar nature will be created from the data, the MHDO may, in its discretion, upon request, waive the requirement that any subsequent report or reports be provided to the MHDO prior to release by the requesting party. In making such a request, the requesting party shall provide the MHDO with sufficient information to determine whether the subsequent report(s) will create a risk of direct or indirect identification of individuals or place an individual health care claims processor, health care facility, or health care practitioner at an economic disadvantage.

Reports provided to the MHDO under this subsection shall be considered confidential agency data.

- (ix) Subsection 9(B)(2)(b)(viii) shall not apply to a requesting party that:
- a.* is an agency of the federal or a state government in the United States or the federal or a provincial government in Canada;
 - b.* is subject to a statute, or a rule adopted pursuant to statutory authority, that prohibits the agency from releasing those portions of the data in its custody that would have a possibility of indirectly identifying patients within the meaning of paragraph 9(A)(2); and
 - c.* has responsibility, assigned by statute, for the collection, custody, and release of clinical data.

The exemption established by this subsection shall terminate, and subsection 9(B)(2)(b)(v) shall apply, in the event that the statute or rule described in *b.* immediately above shall be repealed without being replaced by an equivalent provision.

- C. **Modification of Data.** When requested clinical data do not meet the standards set forth in subsection 9(A)(1), the MHDO will inform the requesting party. If the requesting party is willing to pay the reasonable cost of modification, the Executive Director or a staff delegate shall modify the requested data to meet the subsection 9(A)(1) standards.
- D. **Public Health Exception.** Notwithstanding subsections A (2) and (4) above, the MHDO may release identifying data to the Department of Health and Human Services (“Department”) for the purpose of gaining access to medical records and other medical information pertaining to an investigation or research project of substantial public health importance, in accordance with the procedures set forth below.
- 1. Prior to requesting the release of data under this subsection, the Department will prepare a written protocol, describing the public health investigation or research to be undertaken, including the legal authority under which the investigation or research is being undertaken, the qualifications and affiliations of the staff, the background of the study, the research questions, the research design, case definition and

selection, control definition and selection, if any, study resources, study operational description and data analysis methodology.

- (a) The protocol must ensure that medical information about patients identified by name is not sought from any person without the consent of that patient, except that, if supported by the specific finding set forth in subsection 9(D)(8)(g), the protocol may provide that information pertaining only to the verification or comparison of health data that the agency is otherwise authorized by law to collect may be obtained without patient consent.
 - (b) The protocol prepared by the agency shall also describe the procedure for obtaining patient consent to examine medical information, including the manner in which contact will be made with patients and the practices that will be followed to preserve the confidentiality of any medical information that can be associated with an identified patient.
 - (c) The protocol will be designed to ensure that identifying information released by the MHDO will be used only to gain access to medical records and other medical information for public health purposes identified in the document.
 - (d) The protocol will be designed to ensure that any identifying information released, with or without consent, shall be subject to all confidentiality requirements established in this section.
2. Each person who seeks access to data released under this subsection must agree in writing to comply with the conditions set forth below before receiving any such data, and thereafter shall comply with the conditions set forth below as well as the conditions set forth in subsections 9 (B)(2)(b)(ii) and 9 (B)(2)(b)(v).
- (a) The data released will be used by the Department and its employees only for the specific purposes described in the protocol approved by the MHDO in accordance with this subsection.
 - (b) Medical information about any patient identified by name shall not be disclosed to any other person, other than another investigator who has agreed to the conditions set forth in this paragraph and is subject to such supervision by the Department as is necessary to ensure compliance with these conditions,

without the patient's consent, unless the protocol specifically authorizes verification and comparison without consent in accordance with subsections 9(D)(1)(a) and (8)(g).

- (c) Medical information about an identified patient will be used to the minimum extent necessary to accomplish the purposes of the investigation.
 - (d) The identifying information released will not be used as a basis for legal, administrative, or other actions that may directly affect identified patients as a result of their identification in the investigation, except with the express consent of the identified patient.
 - (e) Unless specified in the original protocol, no follow back investigations to obtain additional information from patients will be undertaken without obtaining additional authorization under this subsection 9(D).
3. Each protocol prepared in accordance with subsection 9(D)(1) must be submitted to the MHDO with a request for approval of the release of the data required to undertake the proposed study. The request shall be accompanied by written agreement to all of the conditions set forth in subsection 9(D)(2), signed by each person who will be given access to the released information.
4. After receipt of a request filed pursuant to subsection 9(D)(3), the MHDO shall notify each affected data provider that identifying data has been requested and may be used by the Department for purposes of identifying individual patients. The notice will include a copy of the proposed protocol and will describe the procedures set forth in this subsection and summarize the nature of the proposed investigation or research. Each affected data provider may file written comments within twenty (20) days after service of the notice, with respect to:
- (a) the adequacy of the protection provided to patient confidentiality;
 - (b) the purposes for which the information will be used; and
 - (c) the extent to which public confidence in the protection of medical information is adequately ensured.

If necessary to address concerns regarding public confidence in the confidentiality of clinical data, comments from the general public or persons known or expected to be interested in the investigation, research or the requested data may also be sought.

5. The Department submit the protocol prepared in accordance with subsection 9(D)(1) for review and approval by an independent advisory body that has been charged with responsibility for approving the protocol, overseeing the investigation to ensure consistency with the protocol and this Chapter, and assessing the scientific validity of the investigation and its effects upon patients. The composition and organization of the advisory body shall be approved by the MHDO. At a minimum, the advisory body must include two consumer representatives and two health care practitioners in the field related to the investigation or research. The Department may submit the proposed protocol to the advisory body at the same time that it files the protocol and its data request with the MHDO under subsection 9(D)(3), or at any time thereafter.
6. Comments filed with the MHDO in response to the notice issued under subsection 9(D)(4) will be forwarded promptly to the advisory body charged with review of the protocol. The advisory body, after review of the protocol, any comments filed, and any issues or concerns raised by its own members or by the MHDO may recommend revisions of the protocol and may require such revisions as a condition of its approval.
7. If necessary to ensure that the standards and conditions set forth in this subsection will be met, the MHDO may request that additional information or comments be provided by the requesting party and any other persons interested in the proposed investigation, research or the requested data. An informal, oral hearing may be held, if necessary to resolve issues raised by the comments and other information submitted.
8. The MHDO shall authorize the release of identifying data not otherwise permitted under subsection 9(A)(1), and the use of information that may be released under subsections 9(A)(2) and (4) for the additional purposes specified in this subsection, upon the conditions specified in subsection 9(D)(3), if, upon review of the information received, the MHDO finds the following:
 - (a) that the protocol required under subsection 9(D)(1) has been prepared, reviewed, and approved by an advisory body in

accordance with this subsection and that the protocol conforms with all applicable requirements of this subsection 9(D);

- (b) that the proposed identification of or contact with patients does not violate state or federal law nor diminish the confidentiality of medical information;
- (c) that the public's confidence in the protection of medical information will not be diminished in a manner that outweighs the expected benefit to the public of the proposed investigation;
- (d) that the sole purpose for which information released under this subsection will be used is to obtain medical records and other medical information necessary to the performance of an investigation that is designed to accomplish public health research of substantial public importance where failure to conduct such research may result in serious harm to patients or other individuals;
- (e) that the Department and each person who will have access to the data under the auspices of the applicable Maine state agency have agreed in a writing filed with the MHDO to adhere to the conditions set forth in subsection 9(D)(3);
- (f) that the Department has demonstrated that it can and will faithfully adhere to the conditions established in this subsection and has in place procedures to ensure such adherence by the agency and its employees; and
- (g) that medical information about any patient identified by name will not be sought from any person without consent of that patient, unless:
 - (i) the information sought pertains solely to verification or comparison of health data that the Department is otherwise authorized by law to collect;
 - (ii) the manner in which such verification and comparison is carried out is consistent with all applicable requirements of this subsection 9(D); and

- (iii) the confidentiality of medical information and the public's confidence in the protection of that information will be adequately protected without patient consent.

10. Review of Requests for Financial or Restructuring Data

Financial or restructuring data shall be released after it has been reviewed in accordance with the provisions of this section.

- A. **Review by the MHDO.** The Executive Director or a staff delegate will review the financial or restructuring data request to determine whether it meets the following standards:
 - 1. Confidential financial data, confidential restructuring data, or protected information are not included in the data to be released; and
 - 2. The data to be released shall not in combination with data in the possession of the requesting party result in the data provider being placed in a competitive economic disadvantage.
- B. **Release of Financial or Restructuring Data.** Data that meets the provisions of subsection 10(A) shall be prepared for release to the requesting party. The release of the financial or restructuring data shall conform to the external review provisions described in section 12.

11. Review of MHDO Reports and Compilations that May Contain Confidential, Privileged, or Protected Data

- A. **All Reports and Compilations.** The Executive Director or a staff delegate shall review every report or data compilation prepared by the MHDO from information in its possession or control, to determine whether any portions of the document contain confidential, privileged, or protected data, or data claimed to fall into those categories. Any such portions will be clearly labeled before the document is deemed final, and the cover of such documents shall state that confidential, privileged, or protected data will be found therein.
- B. **Determination of Privilege or Confidentiality.** Should the MHDO or its staff question any claim of confidentiality or privilege with respect to data used in any compilation or report, the Executive Director or a staff delegate may initiate the review process set forth in section 7.
- C. **Studies, Analyses, and Reports.** In addition to the review described in subsection 11(A), the MHDO shall provide notification of studies, analyses or reports

prepared under 22 M.R.S.A. Sec. 8704(1)(D) to every affected data provider, at least twenty (20) days before such documents are deemed final or made a part of the MHDO's records. Where such documents are to be disseminated to the public, the MHDO's notification shall include:

1. the date that the study, analysis, or report is expected to be made public;
2. the places at which a copy of the study will be available for review on the MHDO web site (<http://www.maine.gov/mhdo>);
3. the price (not to exceed actual cost of reproducing and mailing the study) and means of obtaining a copy of the study; and
4. the affected data provider's right to file comments on the document with the MHDO before that date. Any such comments that are filed shall be stored by the MHDO with the original or master copy of the study, analysis, or report to which they are directed and shall be released upon request.

12. External Review of Data Recipients/Requests

- A. **Data Recipient/Request List.** The MHDO shall create a page on its web site (<http://www.maine.gov/mhdo>) that lists the identity and address of all parties requesting clinical, financial, restructuring, or prescriber data with a summary of each data request. The MHDO shall update the list on the first business day of every week. In addition, through a written request to the MHDO that must include a valid electronic mail address, a data provider or other interested party shall be automatically notified of any new data requests via electronic mail.
- B. **Comments.** Data providers or other interested parties may submit to the Executive Director comments related to the requesting party and/or the proposed use of the data. To be considered, comments must be received by the Executive Director in writing or via electronic mail no later than ten business days after the identity of the requesting party first appears on the MHDO web site. For all data requests that include identifiable practitioner data elements, with the exception of those for prescriber data, or the insured group or policy number, data providers or other interested parties shall have thirty business days to submit comments.
- C. **MHDO Determination.** If the Executive Director determines that:
 1. The comments are of significant importance to delay the release of the data;

2. Additional information is required from the requesting party to address the comments;
3. The data request includes identifiable practitioner data elements; or
4. The data request includes identifiable group or policy numbers;

then the data shall not be released until the additional information has been received from the requesting party and an additional review is conducted by the MHDO to ensure that the requesting party conforms to all applicable requirements of this chapter. The Executive Director may establish a data advisory committee composed of two members of the MHDO Board, two members of the Maine Health Data Processing Board, and such other individuals, as determined by the Executive Director, with relevant expertise to assist with the additional review of the data request. If the data request includes identifiable practitioner data elements, the Executive Director shall establish a data advisory committee composed of two members of the MHDO Board, two members of the Maine Health Data Processing Board, a representative from the Maine Quality Forum, and representatives from the Maine based practitioner professional associations and/or affiliated medical specialty organizations associated with the potentially impacted practitioners. If the data request includes identifiable group or policy numbers, the Executive Director shall establish a data advisory committee composed of two members of the MHDO Board, two members of the Maine Health Data Processing Center Board, a representative of an employer or a business organization potentially impacted by the request, a Maine based representative of consumers, a representative of a Maine based third-party payer organization, and a representative of the third party payer potentially impacted by the request. The requirements of this subsection shall not apply to the release of prescriber data.

13. Protective Orders

On its own motion or that of its staff or a data provider, the MHDO may enter a general protective order governing specified items of data. Such an order shall be granted whenever a similar order would be permissible in the course of formal MHDO proceedings or under the Maine Rules of Civil Procedure and Maine Rules of Evidence. Any data that are subject to such an order shall be labeled by the moving party with the words "protected data" or an equally clear indication that it is subject to a protective order. When general protective orders are requested outside of the context of either discovery proceedings or particular requests for data under this rule, the MHDO may issue them *ex parte*, subject to subsequent reconsideration on motion of any party aggrieved thereby.

14. Compliance

- A. **False Claims or Labels.** It shall be a violation of this rule to claim and label, in accordance with subsection 6(A), data that do not fall within the scope of the definitions in subsections 2(C), (N) and (R), unless the contention of the data provider that data which fell within these subsections were, although incorrect, substantially justified.
- B. **Advanced Protective Order.** Any data provider that violates this rule in the manner described in subsection 14(A) shall be required, in all submissions made with the MHDO for one year following an order finding a violation, to obtain a protective order in advance of the date of submission for any data claimed to be confidential or privileged. All data submitted without such an order shall be released on request. Any motion for such an order shall be made at least thirty days in advance of the required submission date.
- C. **Second Offense.** The penalties provided in 22 M.R.S.A Sec. 8705-A shall apply to a second offense under subsection 14(A), and to any other violations of the requirements of this Chapter.

15. Relationship to Discovery

- A. **Request for Data.** Inquiries that purport to be requests filed pursuant to this Chapter but actually seek data in the form and character of discovery in a pending proceeding before the MHDO or a court or administrative proceeding to which the MHDO is a party shall not be deemed to be requests for data. Such inquiries will be processed in accordance with the rules of practice applicable to the case to which the discovery would apply.
- B. **Confidential, Privileged, or Protected Data.** Nothing in this Chapter shall limit or modify the right of a directly interested person to seek discovery from a data provider of data that may not be released by the MHDO under this Chapter. The MHDO may order such discovery with any protective restrictions that may appear necessary, pursuant to such rules of practice as the MHDO may adopt.

16. Final Agency Action

A party aggrieved by a final action of the MHDO under these rules has the right to judicial review pursuant to 5 M.R.S.A., chapter 375, subchapter VII and M.R.Civ.P. 80(C). For purposes of this rule, the term "final agency action" means an action, or the failure or refusal to take a requested action, of or by the MHDO. Unless otherwise provided for by statute, an aggrieved party shall file a petition for judicial review of final agency action of the MHDO no later than thirty (30) business days after receipt of notice of MHDO action, or the failure or refusal of the MHDO to undertake a particular action.

STATUTORY AUTHORITY: 22 M.R.S.A. §8704, sub-§4 and §8707

EFFECTIVE DATE:

June 27, 1984

AMENDED:

October 5, 1987
April 24, 1991
November 5, 1991
July 6, 1994
January 1, 1995
February 17, 1998

NON-SUBSTANTIVE CORRECTION:

April 8, 1998 - insertion of "and" at the end of §2(C)(2)(b).

AMENDED:

February 13, 2000

NON-SUBSTANTIVE CORRECTIONS:

March 13, 2000

AMENDED:

August 9, 2003 - filing 2003-244, major substantive

NON-SUBSTANTIVE CORRECTIONS:

September 8, 2003 - removal of stray spaces

AMENDED:

August 6, 2005 – filing 2005-278
January 1, 2007 – filing 2006-209, major substantive
June 22, 2008 – filing 2008-227, major substantive
August 15, 2009 – filing 2009-366, major substantive

Appendix J. Comments received on earlier draft reports

Comment #1 on the February 8 draft report from Elizabeth Mitchell of the Maine Health Management Coalition on February 12, 2013

The narrative and policy case are greatly improved in this draft and reflect broader needs and uses of the data beyond quality improvement including evaluation, measurement, consumer choice and payment. To ignore these uses would put Maine significantly behind the national debate and direction and their inclusion strengthens the report.

Despite improvements in the narrative, the recommendations are wholly inadequate to meet the stated aims. Though the 'Voice of the Customer' process was appropriate and is well documented, what the customer requested has seemingly been ignored.

- The report acknowledges that it will not make any recommendations regarding access to PHI though this was a primary purpose of the workgroup.
- The MHDO Board notes the process it is undertaking to improve its responsiveness yet fails to acknowledge that an overall lack of accountability generated the need for the original legislation and the workgroup. We are asked to defer future action to the Board and presume we will have a different outcome than past experience. While we support the steps MHDO is taking and we are hopeful that it will lead to improvement, there are no recommendations on what to do if improvements are not achieved other than 'continued public attention'.
- Also of concern is the tautological argument that resources should follow historical investments- that because we have invested in a service, organization or infrastructure in the past, we must continue to invest in that same service, organization or infrastructure regardless of its effectiveness or relevance to the future state. A key purpose of the original bill and the workgroup was to identify more efficient and effective uses of resources to provide data. The conclusion of the group seems to be that no current roles or relationships should change regardless of cost, effectiveness or efficiency.

Comment #2 on the January 4 draft report from HealthInfoNetmail on January 11, 2013

Overarching Public Policy Case for the Increased Use of health Care Data for Improvement in Health Care

Administrative data (claims data) is not by itself sufficient to evaluate quality and costs of the health care system at the individual consumer, provider, practice, hospital or payer levels. Similarly, clinical data is not by itself sufficient to evaluate quality and costs of the health care system at the individual consumer, provider, practice, hospital or payer levels. Accurate, available administrative and clinical health data that is accessible (with strict safeguards and confidentiality requirements) to patients, providers, purchasers, payers, and researchers is necessary to analyze our current health care system and guide future development for overall improvement in population health and efforts toward a sustainable health care system.

Comment: No details are provided on why administrative data is not sufficient for providing a fairly robust basis for data and analytics on utilization, episodes of care and quality indicators. Significant studies have been done in these areas using administrative data. MHDO, MQF and others have not provided timely data and/or analysis of the administrative data to date. The performance of MHDO in processing, managing, and providing data does not present a convincing argument for expanding their data collection efforts by adding a much more complex and high volume database to the MHDO databases that appear to have limited requests from users (42 requests in 2012 – 13 requests for claims data, 20 requests for IP/OP, 9 requests for other data). More work is needed to improve the operations of MHDO and expand the use of the existing data before any additional statewide databases should be added. Adding more data doesn't solve the problem of limited use of existing databases. Also, throughout the LD1818 report and in these recommendations, statements are made on the value of the linked claims and clinical data. While this is broadly viewed by policy makers and others as true, no reference to published studies, other states' experience or private sector experiences in this area or any empirical evidence is provided to support these statements. Just because someone says it, doesn't make it true. As such, prior to any requests made to the Maine State Legislature, an objective third-party factual/empirical review should be recommended to provide a projection of value relative to what we are trying to accomplish by bringing forward specific proposed changes in structure and statute. This type of work (conducted by an accounting firm and subsequently by a University) was essential to engendering support and demonstrating the potential value of a Statewide Health Information Exchange in Maine. These studies were provided to the legislature as background information for requested changes to Maine State Law and appropriations for HIE efforts, that were critical to the success of HealthInfoNet over the last five years. Without this type of information the legislature has very little evidence to support the changes to legislation and rule making discussed in this report and little justification for financial support.

Four general themes related to governance, data protocol, consumer engagement and protected private health information emerged.

Comment: *There is no effort to connect these themes with the intent of the Resolve and the four specific questions asked in the Resolve.*

Theme 1 Recommendations: Governance

- 1) **There is consensus that there is significant value in linking clinical and claims and other data. This may be achieved through one or more databases. Action: Examine the current relationship and contrasting roles of MHDO and HIN to determine and build the framework needed to serve the public's interest in improving quality, accuracy, and timeliness and access to, clinical, claims and other health care data. Linking claims and clinical information shall meet a set of security and technical capabilities established by current industry standards.**

Comment: *What are the contrasting roles of MHDO and HIN? HIN has been built on a multi-stakeholder governance model with strong participation by the State in providing funding and collaborative support for the development and implementation of a statewide HIE. HIN has been working closely with MHDO on a project to test the feasibility of linking claims and clinical data. Who has determined that the public's interest isn't currently being met? Why is there any need for additional legislative action at this time to develop a working relationship between these two organizations as they work toward determining options for optimizing a structured relationship between the clinical and claims databases? Many sweeping statements are made throughout the LD1818 Workgroup report and in these recommendations without background or supporting details.*

- 2) **We desire a single point of accountability and oversight that would be conducted by a government agency. The MHDO is the steward and setter of policies on claims and quality data and an existing governmental structure that could provide this single point. To better carry out public interest functions, the MHDO Board needs to be reconstituted to be held accountable and to carry out the public oversight (promulgate rules) of clinical, claims and other sources of data. Action: Amend State law which currently gives MHDO general oversight of health care claims and quality ~~and~~ data, to include oversight of clinical health care data. Amend State law to reconstitute MHDO Board to be accountable and to carry out the increased role of public interest by having 8 Directors--a representative of a hospital, healthcare professional, consumer, payer, MaineCare, CDC, OSC, and PFR. Amend State law to continue the Office of the State Coordinator for Health Information Technology in the Department of Health and Human Services and to serve as a co-chair of the reconstituted MHDO Board. Amend State law to move the existing Maine Quality Forum responsibilities to the MHDO.**

Comment: *Who is "we" and what is the need for and advantage of a single point of accountability? HIN is one of the most successful statewide HIE's in the country with a high volume of participation. The statement that MHDO needs to become accountable for "oversight of clinical health care data" is too vague in its intent. This will be point of departure and political*

opposition to these recommendations from multiple stakeholders. Why is accountability needed for the clinical data when a successful system for collecting the data is up and running and the construction of a data warehouse with plans for making data available is underway? How does the proposed approach “better carry out public interest functions”? Amending the current regulations to require the filing of the clinical data by the providers will cause the providers to fight against that requirement and threaten the existence of the statewide HIE. Once the public knows a governmental agency (MHDO) will have oversight authority of their clinical data and will have full access to the personal identification in the clinical data, there is a high probability of the opt-out rates increasing significantly. With each opt out, gaps in the statewide data are created and puts into question the value of the data for linking and for analytic use. Many of the recommendations appear to be building a larger and more robust government agency at a time when there is no state funding to support these efforts. How will this new combined agency be funded and what additional resources will be needed to support this operation? Has there been any evaluation of the Maine Quality Forum’s (MQF’s) value and the need for its continuation? The data on its website is very old and the tables provided are not user friendly. Prior to merging and/or continuing the existence of the state agencies identified, will any performance evaluation be conducted? Given the state budget situation and limited funding from other sources, is this the right time to build bigger?

- 3) **There needs to be a mechanism for the submission, release, disclosure, use of clinical, claims and other data that is as comprehensive as possible, recognizing that improvements in technology will allow ever increasing data flow possibilities. ACTION: Enact legislation requiring MHDO to conduct major substantive rulemakings consistent with legislative guidance to develop mechanisms and processes for the appropriate submission, use, and release of health care data and to establish proposed rates, fees, subscription, or other financial models. The rules should address the submission of data and reporting requirements, to include clinical, claims and other data, and reporting by various sources such as providers, and payers and other sources currently reporting to the APCD and MHDO. The rules should determine the appropriate use (disclosure or exchanges, etc.) of clinical, claims, and other data (raw data, not analytics) and include descriptions and definitions of 1) appropriate requesters (i.e. payers, ACOs, Value-Based Purchasers, Consumers, Researchers, etc.); 2) appropriate release of a) de-identified or aggregated data; b) "minimally necessary" PHI for treatment, payment, and operations as those terms are defined under the HIPAA, and other federal or State laws or rules, and CDC laws and rules; and 3) the specific review, approval, and appeals process for the request of clinical, claims, and other data. MHDO should use existing accepted MHDO rule formats where practical and should consider reduced burdens for submission requirements similar to exemptions under State rules for small businesses. Focused stakeholder discussions with hospitals and key providers should be convened to clearly document issues and concerns associated with mandatory requirement to submit clinical data to a SDSW HIE. As part of this effort, the MHDO needs to identify**

what data elements and metrics should be requested without duplicating what is already collected under current rules.

***Comment:** MHDO already has a set of regulations that cover all of the above for all of the data mandated by them. The only data that is not addressed in MHDO rules is the clinical data as collected by HealthInfoNet. The report and recommendations never define exactly what new data MHDO would govern if they were to mandate the HIE data. It might be worthwhile to identify the specific data elements that would be involved, e.g. problem list, allergies, lab results, radiology test results, etc. and most importantly the patient identifying information including name, social security #, full address, etc. No other database currently governed by MHDO has that level of identifying information. HIN has drafted policies and procedures for providing access to the clinical data. It has not been proven that the current system is not working for management and use of the data but this set of recommendations seems to ignore any work by HIN in this area. Nowhere in the LD1818 Workgroup report or in these recommendations, is a financial estimate provided for how much it will cost for MHDO to take on this added database, which would be the largest and most complex database MHDO would manage. There is also no discussion about how a "statewide file" would be created. It is one thing for a single provider to file mandated clinical data but how is the data going to be normalized and mapped to create a comparative statewide file? Last, "mandating" the filing of clinical data and introducing oversight authority by a governmental authority will jeopardize the trust between HIN and the health care providers participating in the exchange and HIN and Maine health care consumers. The HIN exchange is fairly new and the building of trust has been a challenge, which has been met, but it is new and could be easily destroyed by this type of intrusion on work that is underway successfully in Maine.*

- 4) **Recommend that the highest regard must be taken concerning the "Trust" model associated with individual privacy rights, informed consent and personal ability to safeguard protected health information. Except as otherwise provided by law, the decision whether personal medical records are included in a HIE or a claims system if the claims data is "identifiable" should be made by the patient. All patients should have the ability to have (or not have) their personal medical records in a health care data HIE. ACTION: State law should continue to allow the current opt-out and opt-in mechanisms for clinical data. If claims data is maintained in a manner that does not protect a patient's PHI from being viewed, the MHDO rules should determine the feasibility of creating similar opt-out and opt-in methods for claims data, or a mechanism whereby protected health information is not released.**

***Comment:** As stated, patients currently have the option to opt-out of the HIN exchange. The HealthInfoNet Consumer Advisory Committee has been very involved in the development of all policies and procedures to address patient participation and protection. Discussions have taken place in at least two legislative sessions and consensus has been reached on the approach being taken in Maine for patient participation in the health information exchange. If it isn't broken, why fix it? Applying a standard opt-out or opt-in approach to the claims data ignores the authorization agreement between subscriber and payers and will place an enormous burden on payers to manage which subscribers have opted in or out on an ongoing basis. Payers struggle to*

meet the mandate to file claims data for the APCD now. To add more complexity to the mandate would jeopardize the completeness of the data and impact the timeliness of the filings. Unless MHDO intends to change the filing requirement of patient identifiers in the claims from encrypted to specific patient identifiers, the opt-in and opt-out requirement for claims doesn't seem to fit.

- 5) **Recommend that requests for de-identified linked claims and clinical information only be granted to approved users of the information based on the reported uses of the data as well as ability to appropriately safeguard the information. ACTION: Include this provision as a requirement under the rule and mechanisms to insure compliance with this requirement**

***Comment:** Should a government agency determine who should have access to the clinical data? Maine providers have a long history of working collaboratively to provide statewide databases – Maine was one of the first states in the country to have a voluntary statewide hospital discharge database. Maine led the nation with the Maine Medical Assessment Foundation (MMAF), an organization focused on using population-based analysis of medical and surgical rates to analyze physician performance across the state and to identify outliers. HIN is working with providers to take the same approach for access and use of the clinical data. Involvement of the providers in the release of the data allows those with clinical expertise, knowledge of the strengths and limitations of the data, and strict requirements to protect patient confidentiality, that is reinforced with defined financial penalties for failure to manage access to data within federal and state law, to play a key role in determining who should have access to the data and for what purposes. MHDO, as it is now structured, is not subject to these same standards, laws and penalties for data protection, system audit, and breach management/notification.*

- 6) **Accept as otherwise provided in law, protected health information (PHI) should continue to only be viewable for the provision of Treatment, Payment and Operations (TPO) as those terms are used in applicable Federal and State laws, and further subject to the “minimum necessary” provisions of applicable Federal and State laws. Recognizing that there are some uses of "minimally necessary" PHI that are appropriate public health imperatives that do not defile the patient and which can be used to improve health outcomes and quality, their determination of the appropriateness of the uses should include weighing the value of the use with appropriate consumer protections. ACTION: MHDO rules must comply with these principles and must consider and honor the circumstances that the health care data was submitted or exchanged under. In addition to the APA requirements for submitting provisionally adopted major substantive rules, a description of the analysis performed to ensure that the rules comports with these principles must be submitted with the provisionally adopted rules to the Health and Human Services legislative oversight committee.**

***Comment:** This recommendation raises the issue of a government agency having control over data that was collected for treatment purposes. Providers have agreed to expand the use of the HIE data for their operational purposes as well as allow other aggregated data to be released for*

access by the patient through a provider based PHR. Other aggregated data may also be released as long as patient and provider identifiers are protected. Who is the best steward of the clinical data?? ... the providers and the trusted HIPAA business-associate organizations they work with (that are subject to the same standards laws and penalties for data protection, audit, and breach management as the providers) or a governmental agency, who is NOT subject to these rules?

- 7) **Require that linked claims and clinical information only remain identifiable for the purpose of the linking process itself. Once linking is complete, the member information should be de-identifiable and stored in an encrypted state using the highest standards in available encryption technology. ACTION:** The rules must specifically state this requirement; must include processes to ensure that this requirement is met; and must describe audit and enforcement mechanisms for compliance.

Comment: It is unclear why the State should be the party responsible for linking the data and then managing the identifiers available in the clinical data. MHDO does not receive identifying information on the APCD – all identifiers are encrypted. This approach doesn't make sense – why would MHDO be allowed to have access to patient specific identifiers for the clinical data which has much more revealing data about a person when they weren't provided that type of access for the APCD data by the Maine State Legislature?

- 8) **We need to have a viable financial model(s). ACTION:** Report back from MHDO: Conduct a review of the top three financial models for providing claims and clinical data to qualified requestors. The rules should address fee models, including sliding-scale or subscription, consumer education and protection, and rights, responsibilities, requirements, funding opportunities, and oversight. Endorse the use of MaineCare HIT program administrative funds, where appropriate to improve access to health care data and the benefits as outlined in the federal HITECH Act and Meaningful Use programs.

Comment: The financial model should include an immediate estimate of the cost to collect and maintain the clinical data before a financial model for how the data will be released is developed. MHDO has a very low number of data requestors now (see above). Who are the new customers for the linked data and what are the estimates for how much revenue will need to be generated from users as well as State funding? This approach of "build it and they will come" lacks specifics for who are the potential users are, the total costs to the taxpayer, and the revenues that will support it.

- 9) **There needs to be methods for ensuring accountability of the reconstituted MHDO Board. ACTION:** Consistent with the guidance provided by the Theme 4 subgroup, the structure of the State agency (MHDO) should include a mechanism that establishes and leads ongoing multi-level advisory groups with articulated goals and evaluation systems. The advisory groups should represent the broad spectrum of stakeholders at the organization and individual consumer levels. The framework should seek to establish the MHDO as a forum for various other

advisory groups to report their activities to promote efficiency and meaningful outcomes.

Comment: Representation is a worthwhile area for MHDO expansion but accountability and evaluation should be focused on the operational aspects of MHDO. Advisory groups, by definition, do not have the standing to enforce accountability by a Board. They can influence the direction that a Board takes but can not “enforce accountability” as this recommendation suggests. These recommendations call for a vastly expanded MHDO operation and yet there is no detailed evaluation of how MHDO has improved its data management capacity and it does not provide a convincing proposal for how MHDO could meet the needed financial and staffing resources, expertise, and revenue to take on the additional governance and workgroup activities let alone the expanded operational activated suggested throughout this report.

Theme 2 Recommendations: Data Protocols

- 10) **Support the goals of a State health care data provider to be responsive and timely, accurate, accessible, streamlined, and secure; 2. Support the State's health care data provider (MHDO) effort of building on its existing systems to take advantage of newer technologies better suited to meet the changing needs of the market, such as building a highly robust and secure data warehouse; and 3. Support national standards for data collection and distribution as appropriate. NO ACTION RECOMMENDED.**

Comment: A word of caution with this recommendation. Technology is not a cure all for old problems. In fact, new technologies create new problems. MHDO's existing system will be undergoing a major change this year as MHDO moves from its existing vendor to a new vendor and its partners. The new vendor and its partners do not have any APCD processing or management experience, requiring a much more hands on approach by MHDO and its staff. Based on the complexity and volume of this new work, it is expected that MHDO will be stretched very thin to just transition the existing data systems and databases. Is this really the best time to position MHDO to take on the responsibility for a larger, more complex database than any of their current databases? The timing of the MHDO data has been an ongoing criticism. Their website still provides very limited data or not the timely data needed by users.

Theme 3 Recommendations: Consumer Engagement

- 11) **Balance Consumer Privacy considerations regarding the safeguarding and disclosure of Protected Health Information (PHI) with the societal imperative to drive higher quality and more affordable health care. ACTION: Enact rules and policies consistent with the opt-out and opt-in described in Theme 1 Governance section.**

Comment: There are provisions in place that address opt-out and opt-in. What are the reasons for this recommendation? Is something not working currently? Is a governmental agency the best place for this work?

- 12) **Consumers must have tools available to them to become active engaged consumers. Patients must have the tools available to access their personal health**

records in a variety of ways that build on existing sources. Patients must be given opt-in and opt-out options. **ACTION:** The MHDO should consider ways of providing consumers "digital access", at no charge, to their personal health records. This is critical to the "value chain" as consumers consider whether or not to allow their clinical data to be collected. (The digital access may be in several forms-- telephone, portal, internet--and should build on existing and emerging technologies and may be provided a variety of sources (health care providers, MHDO, HIE, or other entities.)

Comment: Doesn't this function contradict Theme 1, #7 recommendation? If patient identifiers are stored in an encrypted manner after linkage to claims, how will MHDO provide patient specific data via a PHR to consumers? This function would require the management of a patient specific file with a Master Patient index across all providers in Maine. This is a VERY different approach than stated throughout these recommendations. This recommendation also ignores the work currently underway by providers to provide patients access to their personal health records. HIN is working with several providers to provide all inclusive patient specific data. There is also a Centers for Medicare and Medicaid (CMS) Meaningful Use Program requirement that addresses this provision. How will this recommendation interface with that requirement? Again, how will the cost of providing this capability be paid for by MHDO? HIN has collected multiple estimates for providing a statewide PHR and they are significant. This provision by MHDO could also be very confusing for patients and it will most likely raise major concerns regarding confidentiality and security. A PHR would require the management and access to patient specific data with a fairly sophisticated system for linking a patient's records and displaying them in a user friendly system. MHDO does not have the experience or funding to take on this type of responsibility. As was stated earlier in this review document, the prospect of a state agency managing person identified clinical information assumes a trust framework with Maine residents that needs to be questioned and validated before bringing forward this recommendation that has significant public policy implications and a likelihood of broad and intense political opposition.

Theme 4 Recommendations: Protected PHI

- 13) **The structure of the State agency (MHDO) should include a mechanism that establishes and leads ongoing multi-level advisory groups with articulated goals and evaluation systems. The advisory groups should represent the broad spectrum of stakeholders at the organization and individual consumer levels. The framework should seek to establish the MHDO as a forum for various other advisory groups to report their activities to promote efficiency and meaningful outcomes. **ACTION:** The legislature should require MHDO and interested stakeholders to develop a framework for the MHDO to become the forum for the advisory groups. The framework should include specific mechanisms to measure the success of collaborative efforts.**

Comment: Similar recommendation as Theme 1, #9.

Comment # 3 on the January 8 draft report from the Maine Health Management Coalition

On behalf of the Maine Health Management Coalition and its Foundation, we are submitting the following responses and recommendations for your consideration as you revisit the final report of the LD 1818 Workgroup. As you will recall, the Coalition submitted the original legislation that resulted in the workgroup out of growing concern and frustration about the necessity of data to transform care and the inability of data users to access needed data. The Coalition's Foundation Board has been actively involved and have dedicated significant staff time and resources to participate in the workgroup and have submitted our positions to contribute to this process. We remain committed to the workgroup process and are submitting feedback on the proposed recommendations that we hope will inform decisions as they reflect carefully considered input from a broad multistakeholder group of large public and private employers, providers, unions and others.

The Maine Health Management Coalition was founded over 19 years ago with the primary function 'To assist the Members in the process of sharing and analyzing data ("Health Data"), related to the provision of health and related services to the Members, and their employees and health insurance plan participants ("Health Services)". The Coalition now represents 65 members with over 200,000 covered lives - nearly 40% of the commercial market in Maine. The Coalition and its members have been active and engaged users of data for nearly two decades with a membership that is knowledgeable about the current environment and challenges of data access and use. Coalition members recognize and appreciate the tremendous contributions of the Maine Health Data Organization to their work while also recognizing the dramatically different market and demands for data from when the MHDO was created. The Coalition proposes that the State build on the legacy and structure of the MHDO while not limiting us to the historical design and functions. Coalition members remain committed to effective use of data to improve the value of healthcare for all stakeholders in Maine.

Providers need timely data to effectively manage their patient populations and to be accountable to and for the communities they serve. Patients need data to understand the variation in healthcare quality and costs and be educated and informed consumers who can effectively partner with their care team. Purchasers need data to ensure the care they purchase on behalf of their employees and their family members is of the highest quality and value.

The Maine Health Management Coalition (MHMC) and the Maine Health Management Coalition Foundation proposed the following priorities and aims for the development of a statewide data system to support purchasers, patients and providers in the transformation of healthcare and improvement of healthcare value at the outset of the 1818 workgroup process:

1. A common, shared data source of integrated clinical and claims data for all parties to use – with appropriate privacy, security and legal safeguards and role-based access – will serve as the foundation to system and payment reform. All approved users should have fair, affordable and equitable access to the data for the purposes of care improvement.

2. A publicly governed and accountable entity should maintain the functions of the MHDO.

Public governance provides the greatest accountability and protection for data users and could provide fair and equal data access to all users.

3. Timely access to all payer data is necessary to support system transformation. All payer data from commercial and public payers should be available at least quarterly to users. Data on a subset of patients is insufficient to facilitate population health management. Data that is not current does not allow for effective and timely interventions to change care.

4. Patient identified data must be included but identifiable only at the patient/provider level to allow providers to effectively improve care for their patients. Identified data enables the combining of different data sources to allow a meaningful and longitudinal understanding of utilization, care patterns, and outcomes.

5. Resources should be used effectively and care should be taken to avoid unnecessary duplication of data systems and the resources needed to support them. Data is a resource that is only valuable when it is accessible and used effectively.

6. Data users- including consumers- should have input into the structure, design, and purpose of the state's data systems to maximize its use for and by all stakeholders, including the public.

7. Integrated clinical data, claims, health risk, and outcomes data is the optimal source of information for care improvement and high value.

8. Information created from healthcare data should be made transparent and publically available in aggregate with the appropriate safeguards, processes, and criteria for reliability.

We believe the workgroup report and recommendations largely reflect these principles and we are in general support. However we ask that the workgroup also consider the following items:

1. The recommendations should consider a broader range of data sources.

Recommendations acknowledge 'several data repositories' but only name two sources of data in the state, MHDO and HIN. Several more data sources exist including direct data from providers and other private clinical and claims data repositories and should be considered as possible partners in the Maine's data system. The workgroup should think more broadly about options for data and data submissions.

2. The recommendations should include an employer and/or plan sponsor on the reconstituted MHDO Board. We support the recommendation to reconstitute the MHDO Board but the recommendations do not acknowledge the key role of employers as data users and stakeholders with strong interest in a more efficient healthcare system.

3. Linked data should be available and identifiable for multiple purposes. The recommendation to allow linked data only to be identifiable for linking is far too restrictive and misses the point of linking data to use the information for improvement. In fact, this restriction is in conflict with using the data for treatment, payment and operations, the recommendation directly above it, and in conflict with the recommendation in Theme 3 giving consumers access to their own information.

As stated in our original letter, we believe the Maine Health Data Organization's legal status makes it uniquely well positioned to remain the central source of data collection and management. Data submissions should be received from providers, plans, and any other entity that collects clinical, claims, health risk and functional status data, and the MHDO or its successor should continue to manage the data and serve as the primary source of integrated clinical and claims data for the state. However, we do not believe the MHDO or the Maine Quality Forum in its current or proposed state should develop redundant analytic or reporting capabilities. The purpose of the MHDO has been and should remain collecting and managing data to be used as needed for approved purposes by external parties. Each entity that requests data may have different analytic needs and objectives. It is not desirable to have the MHDO and/or MQF determining the information that is generated from the MHDO data set as it is unlikely to reflect stakeholder and user needs, may be redundant of multiple existing efforts, and runs the risk of 'politicizing' the MHDO and jeopardizing what should be a neutral source of common data. Providing data and providing analyses are separate functions and we believe strongly that **the MHDO should focus its resources on its primary mission of providing timely and reliable data to be used by entities as needed.**

Finally, in the draft report, there are repeated references to the need for data by health care providers to improve healthcare. While we strongly support this point, it is a far too narrow view of needed data uses and users. It is important that we explicitly recognize the need for other stakeholders- particularly consumers- to have access to data and information to improve their healthcare decisions. Data can and must be used for improvement and it should also be used for measurement, reporting, analysis, payment and other purposes by a variety of stakeholders. The report should reflect the need for data by multiple audiences and support for using the data for these purposes.

Comment #4 on January 8 draft by Poppy Arford

Poppy made a number of editing comments on the draft, and suggested adding this language to the report:

It is critical that Maine provide public access to cost and quality of care health data, including state of the art digital access to both. This would include a much improved MHDO Health Cost website (see <http://gateway.maine.gov/MHDO/healthcost/>) and patient portal access for all Maine residents, which ensures that patients' clinical record and individually identifiable health information is secure, protected, and available to the patient (see VA Blue Button <http://www.va.gov/bluebutton/>). Together, this health information will provide Maine people with the tools needed to engage fully, effectively and efficiently in improving their health and accelerating the attainment of the Triple Aim in Maine.

Comment #5 on January 8 draft by Jim Harrison

Jim Harrison made detailed editing comments to the entire report. The following are some of his broader suggestions:

- (1) *I agree that MHDO is making good progress in addressing some of the timeliness issues, particularly with respect to Medicare and Medicaid claims data. Commercial claims data has been delivered on time, refreshed quarterly, for more than two years now.*

Hospital data continues to be a problem from both a quality and timeliness standpoint. Onpoint is only one of a number of hospital data users but I thought our experience as a data user would be illustrative. In January, 2013, we are still waiting for corrected 2011 inpatient data (more than 6 mos overdue). The data were received in October, 2012 but contained quality problems that surfaced in our loading and validation process. The most recently available outpatient data is for 2009 (more than 30 mos overdue).

- (2) *I don't believe MHDO's vision/goals can be realized through a new technology platform alone. Seldom does technology solve underlying operational problems, like those identified around process, data, and people in the December, 2010 Deloitte study commissioned by the MHDO.*

The MHDO's approach to development of this new technology platform also introduces a greater level of risk when compared to alternative models. They have chosen a custom-build approach, which has clear benefits but also can lead to delays and cost overruns. That was the case with the recent MaineCare system problems. The MHDO has also selected a vendor that has no track record in the development of APCD systems. I am sure they are aware of these risks and will seek to mitigate them; I raise them here because the workgroup's specific charge was around assuring timely, accurate, and cost effective structures and protocols.

In terms of enhancements to the report, I'd suggest:

- *Background information be provided, including the progress to date meeting the Deloitte recommendations*
- *Asking MHDO management to share some of the key milestones, timeline, and, potentially, performance standards they have put in place to ensure successful implementation. This seems appropriate given that this new platform is the cornerstone of the MHDO's vision/goals that was presented*