

Maine Health Data Organization

Rule Chapter 120: Release of Data to the Public

January 7, 2016

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Section I. Basis Statement

This rule change repeals and replaces the current language found in the MHDO's data release rule in order to implement the provisions of PL 2013, Chapter 528, "An Act to Amend Laws Relating to Health Care Data". This rule specifies the permissible uses of the MHDO data; Defines the different levels of data file types, Level I, II, and Level III; the process for which data requests will be reviewed by MHDO; the data release process; public notice of data requests and opportunity for public comments; the appeal rights for data providers; the MHDO Data Use Agreement (MHDO DUA); MHDO internal use of the data; and the security and protection of the MHDO Data.

Section II. Names of Individuals that Submitted Comments

The following is a list of individuals and affiliations that submitted written comments to the Maine Health Data Organization (MHDO) regarding the new proposed data release rule:

- 1. Katarina Horyn, Associate General Counsel, United Healthcare
- 2. James P. Highland, PhD, President, Compass Health Analytics
- 3. Lisa Harvey-McPherson, RN, MBA, MPPM, EMHS, Vice President Government Relations
- 4. Kristine M. Ossenfort, Esq., Director, Government Relations, Anthem Blue Cross/Blue Shield
- 5. Colin McHugh, Senior Vice President, Network Developing & Contracting, MaineHealth

Section III. Summary of Comments Received by Submitter with Proposed Agency Response & Action.

Below is a summary of the comments received by each submitter and the proposed Agency response:

1. Katarina Horyn submitted the following comments:

Comment 1: Revise section 1.1 to exclude the release of data for commercial purposes that would facilitate collusion or anti-competitive behaviors based on data sources revealed in the data release request.

MHDO Response: Section 1 of the proposed rule describes the primary use of the MHDO data which is to produce meaningful analysis in the pursuit of improved health and health care quality for Maine people. The provision goes on to outline acceptable uses of MHDO data. We do not think it is necessary to add to Section 1 that unacceptable uses of MHDO data includes any violation of law such as anti-competitive behaviors including collusion as these are violations of State and Federal laws. We will revise the language in Section 4(2)(H) as follows:

Data recipients shall be responsible for reporting any potential or actual data breaches to the MHDO. Data recipients shall indemnify MHDO for any damages resulting from a data recipient's data breach or other violation of law, and mitigate to the extent practicable all harmful effects resulting from misuse of MHDO data.

In addition, we will include a provision in the MHDO Data Use Agreement that reminds the data recipient that misuse of MHDO released data for anti-competitive behaviors such as collusion is a violation of law. The MHDO will report any such violation in the use of its data to the appropriate authorities.

Proposed Agency Action: Revise language as described above in 4(2)(H) and include provision in MHDO Data Use Agreement as described above.

Comment 2: Add a definition of "Paid Data" defined as <u>"Paid Data" is the carrier's paid amount, prepaid amount and dispensing fee as well as the member's co-pay amount, coinsurance amount, deductible amount, and patient pay amount."</u>

MHDO Response: The term "paid data" is not used in Rule Chapter 120 and therefore we do not need to define it in Section 2, Definitions.

Proposed Agency Action: No further action required.

Comment 3: Add language to 3.1 to include a reference to the Department of Justice (DOJ) and Federal Trade Commission (FTC) Statement and clearly state that payer's propriety and confidential information re- released to the public will be fully protected by MHDO-even treated as a State trade secret.

MHDO Response: The Statement of Antitrust Enforcement Policy in Health Care was published in 1996 and Statement 6 focused on physicians sharing information. The publication of this Statement predates the creation of the MHDO as well as several health care transparency laws that were enacted in the State of Maine over the last several years. The MHDO enabling statutes and these new laws require the promotion of health care cost transparency. The Statement is not a requirement, but rather defined parameters of a "Safety Zone" that the Department of Justice/Federal Trade Commission will recognize as acceptable conduct between providers absent extraordinary circumstances. As such we disagree with the legal conclusion in this comment and note that there are significant and sufficient protections in the rule regarding how MHDO data is used. We do not believe it is appropriate to include a reference to the DOJ/FTC Statement in the MHDO's data release rule that is specifically designed to execute a Maine Statute that promotes the transparency of health care costs as defined in Title 22, 1683. This proposed rule defines the requirements of the Applicant and Data Recipient which include data security and privacy as well as the restrictions on the disclosure and use of the MHDO data. All data releases will be governed by a MHDO Data Use Agreement that will provide adequate privacy and security measures including accountability and breach notification requirements at least equivalent to those required in business associate agreements under HIPAA. As described in section 3(3)(F), the MHDO has the authority to deny any request for data. The decision to deny or limit a request for data is not reviewable outside the MHDO. Lastly, the rule describes the principle of Minimum Necessary which requires data Applicants and Recipients to make reasonable efforts to request and use only the minimum amount of data needed to accomplish the intended purpose of the data request. Lastly as described in Section 10(4) for all data requests the data providers or other interested parties may submit comments to the Agency related to the data request; and as described in Section 11(C), the data provider has the right to take legal action to prohibit the release of data to a data applicant.

Proposed Agency Action: No further action required.

Comment 4: Add language to 3(1)(D) as follows: Data elements related to health care facility or practitioner charges (total charges, line item charges, charge amount) and data elements related to carriers' Paid Data for services rendered shall only be released by MHDO in the average or aggregate in a manner which will prevent 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.....

MHDO Response: Prior to 2003 MHDO released charge data for hospital inpatient and outpatient services/procedures with the release of the hospital encounter data files. Once the Agency began collecting claims data in 2003 (which includes the paid claims data elements at the individual claim level) the concern was raised by the health plans and providers that if the Agency were to release both the charge and paid data elements associated with each claim and or encounter, along with the identity of the health care facility and health plan, the data user would have the information needed to calculate the negotiated reimbursement rate by health plan by health care facility. In order to address the concern of the health plans and providers regarding what they felt was proprietary information, the negotiated reimbursement rate; the decision was

made to suppress the charge data element in both the release of claims data and hospital encounter data and to only release the paid data elements in the claims data. MHDO has been releasing the paid data elements to approved data users which include hospitals, researchers, government and health plans since 2003. All data requests are publically posted on the MHDO website and an e-mail is sent to interested parties notifying them of a new data request. Title 22 Section 8712 (2) requires the MHDO to create a publicly accessible website that presents reports related to payments for healthcare services by health care facilities and practitioners. The provision requires the MHDO to display prices paid by health plan. The release of the financial data is necessary in order for the MHDO to fulfill is legislative purpose of creating and maintaining a useful, objective, reliable and comprehensive health information database that is used to improve the health of Maine citizens and to issue reports, as provided in section 8712. Data Providers have the option to comment on all data request and to appeal on the issue of whether the release would constitute the release of proprietary data as described in Section 11(4).

Proposed Agency Action: No further action required.

Comment 5: Add language to 3(3)(H) as follows: Data elements related to payments may be arrayed or displayed publically in a way that shows <u>only average or aggregate payments</u> for specific health care services by individual health care claims processors, <u>individuals</u> and health care facilities or practitioners only by MHDO.

MHDO Response: The MHDO does not agree that the data which Title 22, 1683, specifically Section 8712 requires MHDO to report needs to be averaged or aggregated. Support for this position also includes the price transparency laws in the State of Maine and the MHDO data releases to approved data users including hospitals, health plans, and researchers over the last twelve years which has included the identification of the payer and the payers' payment information at the claim level.

Proposed Agency Action: No further action required.

Comment 6: MHDO should consider an alternative approach for release of data for commercial purposes that would restrict the release of claims and prescription data fields directly related to pricing, payment, and copayments/coinsurance.

The commenter suggests the following as a potential solution to address the concerns above by redefining Commercial (2(8)) and Non-Commercial Redistribution (2(31)) as follows:

Commercial Redistribution is when a for-profit or not-for-profit business or organization purchases MHDO data or information for inclusion in a larger composite database for resale in any form that does not facilitate collusion or otherwise reduce competition as outlined by the Department of Justice and Federal Trade Commission.

Non-Commercial Redistribution is when an entity purchases MHDO data for inclusion in a larger composite database that is publically released, that does not facilitate collusion or otherwise reduce competition as outlined by the Department of Justice Federal Trade Commission and is available at no cost."

MHDO Response: The Statement issued in 1996 by the Department of Justice/Federal Trade Commission is not a requirement, but rather defined parameters of a "Safety Zone" that the DOJ/FTC will recognize as acceptable conduct between providers absent extraordinary circumstances. We do not believe it is appropriate to include a reference to the DOJ/FTC Statement in the MHDO's data release rule that is specifically designed to execute a Maine Statute that promotes the transparency of health care payments as defined in Title 22, 1683. This proposed rule defines the requirements of the Applicant and Data Recipient which include data security and privacy as well as the restrictions on the disclosure and use of the MHDO data. The proposed rule defines the principle of minimum necessary and authorizes the MHDO to deny any data request as appropriate. As described in Comment 1 we will revise the language in Section 4(2)(H) as follows:

Data recipients shall be responsible for reporting any potential or actual data breaches to the MHDO. Data recipients shall indemnify MHDO for any damages resulting from a data recipient's data breach <u>or other violation of law</u>, and mitigate to the extent practicable all harmful effects resulting from misuse of MHDO data.

In addition we will include a provision in the MHDO Data Use Agreement that reminds the data recipient that misuse of MHDO released data for anti-competitive behaviors such as collusion is a violation of law. The MHDO will report any such violation in the use of its data to the appropriate authorities.

Proposed Agency Action: Revise language as described above in 4(2)(H) and include provision in MHDO Data Use Agreement as described above.

2. James P. Highland submitted the following comments:

Comment 7: Include encrypted member identifiers in Level 1- Commenter is concerned that the data elements currently proposed will provide inaccurate results without this information.

MHDO Response: While there are some analysis that will be able to be done without the encrypted member identifier, we agree it would be helpful to include a de-identified identifier so data requestors can use the Level 1 data to track de-identified members across time, between payers. This may increase the number of data requestors that can use Level 1 data vs. having to request Level 2 (aligns with our minimum necessary standard).

Proposed Agency Action: Add the MHDO assigned Member ID to Level 1 data elements in Appendix A.1 APCD Data Elements and Appendix A.2 Hospital Encounter Data Elements. The MHDO assigned identity number is an internal number assigned to a record that does not tie back to any direct individual identifiers.

Comment 8: Both the current rule and proposed rule require that the Data User submit copies of any report generated from MHDO data to the MHDO for review at least 20-days prior to release. The commenter states this is a barrier to businesses and would require substantial MHDO resources. The commenter suggests that the MHDO follow the CMS policy as described at: https://www.cms.gov/Researchers.html.

The User agrees that any use of CMS data in the creation of any document (manuscript, table, chart, study, report, etc.) ... must adhere to CMS' current cell size suppression policy. This policy stipulates that no cell (e.g. admissions, discharges, patients, services) 10 or less may be displayed. Also, no use of percentages or other mathematical formulas may be used if they result in the display of a cell 10 or less. The users agrees by signing the DUA that they will agree to abide by these rules and, therefore, will not be required to submit any written documents for CMS review.

The commenter suggests if the CMS policy is not adopted the MHDO should reinstate the language in the current rule that waives the requirement for a 20-day review when there are multiple reports of a similar nature.

MHDO Response: The language in section 4(2)(J) is as follows:

At least twenty (20) business days prior to releasing any manuscript, report, or any other type of document or data compilation **intended for dissemination or publication beyond the data recipient** and that contains and/or uses MHDO Data, the Data Recipient agrees to provide the MHDO with a copy of such document. If the MHDO determines that the manuscript, report, or any other type of document violates the MHDO DUA or does not provide adequate data suppression, the Data Recipient will be notified and must modify the report prior to its release.

The intent of this provision as stated above (highlighted in bold) is when any manuscript, report, or any other type of document or data compilation intended for dissemination or publication beyond the data recipient.... We do not believe this requirement is a barrier to businesses since most of the work that is being done with the MHDO data is not for dissemination and or publication beyond the data recipient but rather for internal purposes. For those uses of the data that include dissemination or publication beyond the data recipient we believe the requirement is reasonable. If multiple reports of similar nature are being disseminated or published beyond the data recipient copies of those reports should be sent to the MHDO as described in section 4(2)(J). As the MHDO prepares its new MHDO Data Use Agreement is will consider incorporating best practices from CMS including the policy referenced above.

Proposed Agency Action: Consider the CMS policy referenced above when developing the MHDO Data Use Agreement.

3. Lisa Harvey-McPherson submitted the following comments:

Comment 9: The requirements that data recipients must meet to safeguard MHDO data should be more clearly defined. Examples given, MHDO could explicitly require the same standards that are required by the HIPAA Privacy and Security Rules or some other federal patient data safeguarding standard.

MHDO Response: Title 22, 1683, section 8714 3(B) States that Data releases must be governed by data use agreements that provide adequate privacy and security measures that include appropriate accountability and notification requirements as required of business associate agreements under HIPAA. The language in Section 4(1) states that all data recipients must sign a MHDO Data Use Agreement and that the MHDO DUA shall provide adequate privacy and security measures that include accountability and breach notification requirements as those required of business associate agreements under HIPAA. As part of the application process the data recipient will be required to provide the MHDO with a detailed description of their privacy and security policies and infrastructure. The MHDO will deny the release of data if the policies and infrastructure does not meet the requirements of business associates under HIPAA.

All Data Recipients must sign a MHDO DUA. Only MHDO may use the MHDO DUA. The MHDO DUA is the document that details the data Recipient's commitments to data privacy and security, as well as the restrictions on the disclosure and use of the MHDO Data. The MHDO DUA shall provide adequate privacy and security measures that include accountability and breach notification requirements similar to those as required of business associates under HIPAA. Standard MHDO DUA's shall be published on the MHDO public website.

Proposed Agency Action: Revise the language in 4(1) as described above.

Comment 10: Question regarding why patient names and social security numbers (SSN's) are retained as MHDO data elements. The second question raised, is there another feasible way for providers to identity patients without using SSN's?

MHDO Response: For over ten years the MHDO has been collecting and securely storing social security numbers (SSNs) when available from both hospital and payer data submitters as described in Rule Chapter 241: Uniform Reporting System for Hospital Inpatient Data Sets and Hospital Outpatient Data Sets and Rule Chapter 243: Uniform Reporting System for Health Care Claims Data Sets. The SSN is used to assign MHDO member identifiers (which is an internally assigned number that does not tie back to any individual direct identifier). While it may be feasible to use other facility or payer-assigned identifiers to identify individuals within a given facility or a given payer, it is not possible to use these types of identifiers between facilities or payers. One valuable use of these data for many of our data users is for longitudinal studies- to allow the tracking of individuals across time. Overtime it is highly likely that an individual will be associated with multiple facilities and payers. Without an identifier that remains consistent across time, it is impossible to track an individual. Until there is another such identifier available, such as a National Patient Identifier, the SSN is the only feasible way to accomplish this. The SSN is stored securely and separately from other data elements. The MHDO Data Warehouse resides

within the National Opinion Research Center (NORC) secure facilities. These facilities have strictly controlled physical access and maintain boundary protection utilizing network firewalls, Intrusion Prevention System (IPS) and security monitoring using a unified situational platform. The NORC Data Enclave IT Security Plan is fully compliant with the Federal Information Security Management Act, provisions of mandatory Federal Information Processing Standards (FIPS), and meets all of NIST's IT, data, system and physical security requirements.

Proposed Agency Action: No further action required.

Comment 11: Add language prohibiting further disclosure of MHDO Data by data recipients to subcontractors or other third parties be added to the MHDO DUA.

MHDO Response: In many cases the data requestor contracts with a third party for the data analytics. The third party must be identified in the application process and is subject to the terms and provisions of the MHDO's Data Use Agreement. If the MHDO was to prohibit disclosure of data by data recipients to subcontractors we would be would creating an unfair advantage for those organizations that have the data analytic capabilities in house.

Proposed Agency Action: No further action required at this time.

Comment 12: The proposed rule states that no HIV status, inpatient psychiatric care or federal drug/alcohol abuse program information will be disclosed by MHDO. Question is how this control is assured, particularly in light of the fact that procedure and diagnosis codes are included in the MHDO data.

MHDO Response: Similar to how the MHDO handles the provision in Chapter 120 that prohibits the release of 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, the MHDO will develop a list of ICD-10 and CPT codes that are specific to HIV tests and status; psychiatric treatment records; and substance abuse treatment as describes in Section 3(1)(F)(G)(H). This data will be suppressed from all Level III data releases.

Proposed Agency Action: Develop list of ICD-10 and CPT codes for data specific to HIV tests and status; psychiatric treatment records; and substance abuse treatment as describes in Section 3(1)(F)(G)(H). As stated above this data will be suppressed from all Level III data releases.

4. Kristine M. Ossenfort submitted the following comments:

Comment 13: Section 3(3)(I) of the proposed rule provides that "Authorized Redistributors" of MHDO data "can use the MHDO data for inclusion in a larger composite database or to produce reports that are publicly released." However, the term "authorized redistributor" is not defined.

MHDO Response: Within the definitions of Commercial and Non-Commercial Redistribution is the language regarding inclusion in a larger composite database. As such we agree we need to clarify the language in section 3(3)(I) as follows:

3(3)(I). A data recipient may not sell, re-package or in any way make MHDO Data available at the individual element level, unless the ultimate viewers of that data have applied to MHDO for this data, been approved for such access and signed an MHDO DUA. Authorized Redistributors of the MHDO Data can use the MHDO Data for inclusion in a larger composite database or to produce reports that are publically released.

Proposed Agency Action: Clarify language in Section 3(3)(I) as described above.

Comment 14: Section 3(3)(J) provides that the "MHDO shall maintain ownership of all data elements and sets it releases including any MHDO generated numbers or identifiers therein." However, the MHDO does not really "own" the data. The data is submitted by data providers and the MHDO is the state repository for that information; however, that does not confer ownership rights upon the MHDO. Therefore, we would suggest amending section 3(3)(J) to provide that "<u>As between MHDO and the data recipient, MHDO shall maintain"</u> A similar change should be made to section 4(2)(C) as well.

MHDO Response: Given the authority and responsibility the MHDO has been given per Title 22 Chapter 1683 to collect, process, protect, release, analyze and report on health care data the MHDO asserts that it does legally own the data once it is submitted to the MHDO and passes through the MHDO's internal set of validations.

Proposed Agency Action: No further action required.

Comment 15: Section 4(2)(H) requires that Data Recipients must indemnify the MHDO from any damages resulting from a data recipient's breach. The Data Use Agreement used by the MHDO should also require Data Recipients to indemnify Data Providers—it is very likely that someone whose information was compromised might well take action against the Data Provider as well as the MHDO.

MHDO Response: We will consider this comment when drafting the Data Use Agreements.

Proposed Agency Action: No further action required.

5. Colin McHugh submitted the following comments:

Comment 16: As an organizing framework, MaineHealth is generally supportive of Level III data being made available by the MHDO to Covered Entities as defined in the regulation and subject to HIPAA requirements related to the protection of the privacy and security of health information, permitted uses and disclosures, and limiting uses and disclosures to the minimum necessary. MaineHealth, however, strongly opposes the release of Social Security numbers under any circumstances.

MHDO Response: For over ten years the MHDO has been collecting and securely storing social security numbers (SSNs) when available from both hospital and payer data submitters as

described in Rule Chapter 241: Uniform Reporting System for Hospital Inpatient Data Sets and Hospital Outpatient Data Sets and Rule Chapter 243: Uniform Reporting System for Health Care Claims Data Sets . The SSN is used to assign MHDO member identifiers (which is an internally assigned number that does not tie back to any individual direct identifier). Currently the MHDO is prohibited from releasing names and social security numbers of individual claimants and or patients. One of the primary reasons for drafting a new data release rule is to comply with the PL 528 which allows the MHDO to release direct patient identifiers. The definition of Direct Patient Identifiers is in section 2(15):

Direct Patient Identifiers. "Direct Patient Identifiers" are personal information as outlined in Chapter 125, such as name, social security number, and date of birth, that uniquely identifies an individual or that can be combined with other readily available information to uniquely identify an individual. A MHDO assigned replacement number or code (used to create anonymous data indices or linkage) is not a direct identifier. MHDO Level III Data includes Direct Patient Identifiers.

The release of Level III data which includes Direct Patient Identifiers is described in Section 8 Data Requests from Covered Entities Who Are Data Providers for Level III Data. The decision to release Level III data will be made by the Data Release Subcommittee and will require the applicant to meet all the criteria described in the data release rule as well as the MHDO Data Use Agreement which details the requirements of a data recipient specific to data privacy and security as well as restrictions on the disclosure and use of data. As part of the application process and the minimum necessary principle as defined in Section 2(29), the applicant will be required to justify the need for each of the Level III data elements that are being requested. The data applicant must show that they are requesting the minimum amount of data needed to accomplish the intended purpose of the data request. Additionally, individuals have a choice regarding the disclosure of their direct identifiable health care information as described in Section 13 of the proposed rule. PL 528 was passed because of the current and emerging needs for the release of data elements described in Appendix D of the proposed rule for treatment, payment, and health care operations as defined in HIPAA regulations. Suppressing the release of a social security number for an approved Level III data applicant is counter to the intent of PL 528.

Proposed MHDO Action: No further action required.

Comment 17: clarification of the following underlined statement in section 3(3)(I), "A data recipient may not sell, re-package or in any way make MHDO Data available at the individual element level, unless the ultimate viewers of that data have applied to MHDO for this data, been approved for such access and signed an MHDO DUA. Authorized Redistributors of the MHDO Data can use the MHDO Data for inclusion in a larger composite database or to produce reports that are publically released." MaineHealth strongly opposes the release of PHI for any purposes other than improvement of patient care. The sharing of patient identifiable data for commercial purposes, absent patient consent, is not authorized by HIPAA and conflicts with the federal policy safeguarding patient confidentiality embodied by HIPAA. In no way should such uses be contemplated by the MHDO.

MHDO Response: As defined in Section 6(2)(B) Data requests for purposed of commercial redistribution that are aggregate level reporting including on-line tools, are only eligible for Level I data elements. MHDO Level I data is considered de-identifiable data which means information that does not directly or indirectly identify an individual patient.

Proposed Agency Action: Clarify language in Section 3(3)(I) as follows:

3(3)(I). A data recipient may not sell, re-package or in any way make MHDO Data available at the individual element level, unless the ultimate viewers of that data have applied to MHDO for this data, been approved for such access and signed an MHDO DUA. Authorized Redistributors of the MHDO Data can use the MHDO Data for inclusion in a larger composite database or to produce reports that are publically released.

Comment 18: Given the complexity associated with the proposed Maine Health Data Organization (MHDO) Data Release Rule, MaineHealth believes a more robust oversight and governance process needs to be instituted. The MHDO's process of approving requests for claims data with identifiable patient information should require unanimous approval from the committee charged with reviewing data release requests, and with such approval to be given if -- and only if -- the permitted uses have been properly established and assurances that safeguards will be executed to prevent prohibited or unauthorized uses.

MHDO Response: The MHDO has been releasing health care data to authorized users for over ten years. Given the intricacies of data collection and release, the goal of this proposed rule is clarity; transparency; and alignment with best practices. This rule is a repeal and replace of MHDO's rule on data release, 90-590 CMR Chapter 120, Release of Data to the Public. This overhaul includes several major themes:

- breaks down data sets into different levels based on whether any elements of identifying information are involved;
- includes appendices listing the actual data elements in each data set, which may help public transparency about what the MHDO does;
- clarifies data user's ability to request and receive direct patient identifiers when that is
 necessary for the data user's study and they meet the numerous requirements protecting
 that information.
- clarifies that all data sets released by MHDO, including the "de-identified" or Level I data set require a data use agreement, and approval by the Executive Director, as bottom line protections
- provides a method for subjects of data to "opt-out" of a Level III (Health data with Direct Patient Identifiers) data releases; it clarifies that only charge data at the individual level is confidential and is not released by MHDO except at an aggregate/average level;
- greatly simplifies the review and appeal process for data provider's claims of proprietary information;
- specifies data protections and practices such as "minimum necessary," MHDO DUA's and breach notification, and promulgates the MHDO's ability to levy large fines for misuse of MHDO data for financial or personal gain;

- aligns many existing MHDO practices with the concepts of the Health Insurance Portability and Accountability Act (HIPAA); and
- provides for one Data Release Subcommittee of the MHDO Board of directors, rather than the old scheme of internal and external boards.

We have been working on this proposed rule for over two years and believe it provides a comprehensive description of the data release process and requirements for the release and use of the MHDO data which are more robust in many areas including oversight, governance, and data security and privacy than the existing MHDO data release rule as summarized above.

The proposed rule as drafted requires 4 out of the 6 members of the Data Release Committee to vote in the affirmative to take action (12(3)). The composition of the subcommittee is one member representing each of: health care plans, health care providers, hospitals, employers, consumers and government as described in section 12(2). Consensus is what we will work towards, however; establishing the requirement of consensus governance in the rule allows one view point to veto action. The majority requirement of the subcommittee is consistent with the governance structure of the MHDO board.

Proposed Agency Action: No further action required.

Comment 19: Appreciate the Agency's response to our December 29, 2014 comments concerning the Chapter 120 draft rule. We want to reiterate those concerns related to the release of individually identifiable practitioner data elements and stress the importance of the MHDO ensuring the accuracy and reliability of such data.

MHDO Response: The comments submitted by Dan Morin, Director of Government Affairs MaineHealth on December 29, 2014 that are related to the release of individually identifiable practitioner data elements and the MHDO responses to those comments reviewed and approved by the MHDO board are below:

"Dan Morin submitted the following comments:

Comment: Our first concern is that the proposed draft regulations continue to create ambiguity regarding the potential disclosure of individually identifiable practitioner data elements.... In addition, existing Chapter 120 MHDO rules governing the disclosure to the public of data do not specifically include a direct definition of "individually identifiable practitioner data elements" or include it under the definitions of Financial Data and Quality Data. The only reference to identifiable practitioner data elements falls under Section 12(B) concerning comments in response to the External Review of Date Recipients/Requests.

Agency Response: The purpose of the Maine Health Data Organization as defined in Title 22, Section 8703 are to create and maintain a useful, objective, reliable and comprehensive health information database that is used to improve the health of Maine citizens and to issue reports, as provided in section 8712. This database must be publicly accessible while protecting patient confidentiality and respecting providers of care. One of the purposes of this rule is to specify the

permissible uses of the MHDO data (which includes identifiable practitioner data as submitted by the data submitters in both the claims data and the hospital encounter data) as described in Section 1 (1)... The primary use of the MHDO Data is to produce meaningful analysis in pursuit of improved health and health care quality for Maine people. Acceptable uses of MHDO Data include, but are not limited to, study of health care costs, utilization, and outcomes; benchmarking; quality analysis; other research; and administrative or planning purposes. The MHDO will make data publically available and accessible to the broadest extent consistent with the laws protecting individual privacy of individual's seeking health care services, and proprietary information.

MHDO has been releasing claims data since 2003 and after working with the provider community started releasing identifiable practitioner data in 2005. In fact, Maine Health is one of the users of the MHDO claims data that includes practitioner identifiable data as are several other health care entities.

Sections 6-8 of the proposed rule define the data request process. All data applicants are required to define in their application how they will use the data that is being requested. If the MHDO determines that the use of the data is not consistent with the acceptable uses defined in Section 1 then the MHDO has the authority to deny the data request. In addition as described in Section 10 all data requests will be posted on the MHDO website including the level of data requested and the purpose of the request. Data providers and interested parties have the option to submit comments to the MHDO related to a data request that include practitioner identifiable data as described in Section 10 (4) and data providers have the option to appeal a data release on the issue of whether the release would constitute the release of proprietary data as described in Section 11(4)(C).

Comment: The use of Practitioner Identifiable Data Elements is also not addressed in the body of the newly proposed MHDO Data Release Rule, only in APPENDIX C. This creates further confusion in our opinion. For example, there is neither a definition of the term nor any guidance on the permitted release or eventual public use of individually identifiable practitioner data elements. It is also unclear why the terms listed under Section 5, subsection 1, A through E (MHDO Data Sets available for Public Access) are each defined under Section 2 but Section (5)(1)(F) concerning Supplemental Data under APPENDIX C is not.

Agency Response: It is not the intent of the data release rule to define the hundreds of individual data elements that are derived directly from the APCD Data, Hospital Encounter Data, Financial Data and the Quality Data. The proposed release rule does however list the data elements that are released in the various levels of release files in appendices A-D. Consistent with best practice the MHDO maintains a Data Dictionary which is available on the MHDO website that defines the data elements that are derived from the various data sources. Section 5 of the proposed rule defines the MHDO Data Sets and Data Release Types.

Agency Action: To be consistent we will add Supplemental Data in the definitions section of the rule.

Section 2. Supplemental Data. "Supplemental Data" consists of data elements that are derived directly from the APCD Data and the Hospital Encounter Data. Specifically, Supplemental Data includes the Group ID Data Elements and the Practitioner Identifiable Data Elements as listed in Appendix C.

Comment: While there are defined limitations and requirements under Section (3)(3)(D) concerning requests for Payer Assigned Group ID Numbers under APPENDIX C there are no such limitations and requirements outlined for Practitioner Identifiable Data Elements.

Agency Response: The reason why there are limitations and requirement defined in Section 3(3)(D) for requests that include the Payer Assigned Group ID Numbers is because unlike the Practitioner Identifiable Data Elements which are identified in the source data the Payer Assigned Group ID Numbers are not identified in the source data. In addition, the Payer Assigned Group ID Numbers is a data element that is sensitive and could lead to the identity of an individual receiving health care whereas the Practitioner Identifiable data element is not considered a sensitive data element that could lead to the identity of an individual receiving health care. Consistent with State law Section 3 (1)(E) addresses the issue of maintaining the confidentiality of the identification of practitioners performing abortions.

Agency Recommendation: No further clarification needed.

Comment: Please cite the current statutory and/or regulatory reference and guidance for MHDO to release individually identifiable practitioner data elements.

Agency Response: Refer to Title 22, Chapter 1683, Section 8703 and 8707 (which will become 8714) and Rule Chapter 120. Consistent with 8707 (1) the only practitioners identity that must remain confidential and protected is the identify of practitioners performing abortions. The data elements regarding the identity of individual practitioners have been available for at least the last eight years as a releasable data element in accordance with the existing requirements and protections of Rule Chapter 120."