

Maine Health Data Organization  
January 8, 2015

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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. Kathy Day  
Representing Consumers and various other professional consumer advisory organizations.
2. Dan Morin  
Director of Government Affairs  
MaineHealth
3. Phil Morissette  
CFO & Treasurer  
Central Maine Healthcare
4. Kristine Ossenfort, Esq.  
Director, Government Relations,  
Anthem Blue Cross and Blue Shield

5. Anne Rogers  
Manager, Data and Research,  
Substance Abuse and Mental Health Services, DHHS
6. Andrew E. Smith  
State Toxicologist,  
Maine Center for Disease Control, DHHS
7. Karynlee Harrington  
Acting Executive Director  
Maine Health Data Organization (MHDO)

### **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. Kathy Day submitted the following comment(s):

***Comment:** I would suggest that a second consumer or organizational consumer be added to this 6 member committee, to properly represent consumers and to make it a committee of 7 rather than 6. An even number is a set up for tied decisions.*

**Agency Response:** The MHDO board discussed the issue of the composition of the MHDO Data Release Subcommittee at its October 23, 2014 board meeting as part of its detailed review of the proposed rule. The Consumer Representative on the board suggested that an additional consumer be added to the MHDO Data Release Subcommittee as described in Section 12 of the proposed rule. Several board members expressed their opinion on the matter and stated that the composition of the MHDO Data Release Subcommittee as described in Section 12 of the proposed rule was a balanced group and that the provision in Section 12. (3) appropriately addressed the issue regarding a split decision of the subcommittee.

**Agency Action:** Based on the outcome of the Boards deliberations on this issue no change regarding the composition of the MHDO Data Release Subcommittee is needed.

***Comment:** Any and all information that MHDO holds regarding individual patients, should first and foremost be available to the patients/consumers upon their request.*

**Agency Response:** An applicant can apply per the requirements in the data release rule and any other applicable rule to access MHDO data.

**Agency Action: No further clarification needed.**

2. Dan Morin submitted the following comment(s):

***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 Data 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).

**Agency Action: Revise the definition of APCD Data and Hospital Encounter Data as follows:**

APCD Data. “APCD Data is Health Care Claims Data consisting of, or derived directly from, member eligibility, medical claims which includes identifiable practitioner data elements, 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.

Hospital Encounter Data. “Hospital Encounter Data” means information consisting of or derived directly from hospital inpatient, outpatient, emergency department which includes identifiable practitioner data elements 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 and Emergency Department Data Sets.

***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.**

The guidance provided in the proposed rule regarding the permitted use of MHDO Data is described in Section 1. (1). Authority and Purpose. This section describes the acceptable uses of the MHDO data which include but are not limited to study of health care costs, utilization, and

outcomes; benchmarking; quality analysis; other research; and administrative or planning purposes.

**Agency Action:** No further clarification needed.

*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:* while Section 11(4) outlines the subject of appeal by a data provider should they disagree with an MHDO decision to release certain data and the potential recourse of taking legal action to prevent release, we request additional language be added to clarify that the data will not be released until final adjudication.

**Agency Action:** The intent of Section 11(4)(C) is that the data shall be released unless a data provider takes legal action to prevent the release...

**Agency Recommendation:** Add the following language to clarify the intent of Section 11(4)(C).

**11 (4)(D). In the event that a data provider takes legal action to prevent the release of data as described in Section 11 (4)(C) the MHDO will not release data until a final decision has been made.**

*Comment:* Can MHDO provide information on the purpose of APPENDIX C?

**Agency Response:** The rationale behind Appendix C is that while the data elements listed in Appendix C are available for release in all three levels of data files upon approval by the MHDO, the data elements in Appendix C regardless of the level of release are open to public comments from the data provider and or interested parties. In addition, the data provider has the option to appeal the Agency's decision to release the data elements in Appendix C on the issue of whether the data release would constitute the release of proprietary data as described

in Section 11 (4).

**Comment:** *Why is it being proposed and what is the need?*

**Agency Response:** Refer to response immediately above.

**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.

3. Phil Morissette submitted the following comment (s):

**Comment:** *One of my concerns is that there has been regulated redundancy for the reporting of audit information. It would be great if all regulated efforts within the State of Maine could be coordinated for one submission rather than many and that the appropriate organization be the entity for which such information is collected.*

**Agency Response.** *The audited financial statements collected by the division of audit- DHHS are from the hospital entity only while Chapter 300 requires the submission from both the hospital and parent entity (if applicable). In our continued efforts to streamline the reporting process the MHDO accepts the audited statements electronically in PDF file format and when appropriate we will seek a copy of the hospital audited statements directly from DHHS upon request from the reporting hospital to do so.*

**Agency Action:** No further clarification needed.

4. Kristine Ossenfort, Esq. submitted the following comment(s):

**Comment:** *The proposed definition of the term “disclosure” applies only to protected health information or “PHI”; however, the potential for unauthorized disclosure is not limited to PHI and the restrictions on unauthorized disclosure should not be limited to PHI. In addition, it may the definition should probably pertain to “Unauthorized Disclosure” rather than disclosure.*

**Agency Response:** Agree with comment above.

**Agency Action: Revise the definition in Section 2 (15) as follows:**

Section 2 (15). Unauthorized Disclosure. “Unauthorized Disclosure” means to communicate PHI and any other MHDO Data 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” unauthorized information not already in that person's possession with respect to the patient.

**Comment:** *The definition of “limited data set” indicates it is “similar” to that specified in HIPAA. We believe it should be the same as set forth in HIPAA and would suggest revising the definition as follows:*

*24. Limited Data Set. A “Limited Data Set” includes limited identifiable patient information as similar to that specified in HIPAA regulations. A Limited Data Set may be disclosed to a data recipient without a patient’s authorization in certain conditions: (1) the purpose of the disclosure must be limited to research, public health, health care operations; (2) the purpose of the disclosure must be consistent with and the purposes of the MHDO; and (3) the Data Recipient must sign a MHDO DUA.*

**Agency Response: Agree**

**Agency Action: Revise the definition in section 2 (24) as follows:**

Limited Data Set. A “Limited Data Set” includes limited identifiable patient information similar as to that specified in HIPAA regulations. A Limited Data Set may be disclosed to a data recipient without a patient’s authorization in certain conditions: (1) the purpose of the disclosure must be limited to research, public health, health care operations ~~and the purposes of the MHDO~~; (2) the purpose of the disclosure must be consistent with the purposes of the MHDO and (3) the Data Recipient must sign a MHDO DUA. The identifiable patient information that may remain in a limited data set for MHDO includes:

- A. dates such as admission, discharge, service, Date of Birth (DOB), and Date of Death (DOD);
- B. city, state, five or more digit zip code, and
- C. age in years, months or days or hours.

MHDO Level II Data releases are a limited data set. Limited data sets may only be used in ways that maintain patient anonymity.

**Comment:** *We have several concerns with the definition of “proprietary data.” First, the current*

*version of Rule chapter 120 contains a definition of “confidential data,” which was not carried forward in the proposed rule. While the proposed rule does contain a definition of “proprietary data” not found in the current rule, it is much narrower than the existing definition. The definition also specifically affords confidential treatment to hospital charge information but not the reimbursement rates negotiated between providers and payors. Affording confidential treatment to hospital charge information is contrary to the disclosure requirements of 22 M.R.S.A. sections 1718 and 1718-A.*

*In addition, the definition of proprietary data states that the MHDO will determine if the disclosure of the information will result in the Data Provider being placed at a competitive economic disadvantage—this fails to provide data providers with any form of due process. If the MHDO decides that disclosure would not result in a competitive economic disadvantage, a Data Provider has no opportunity to be heard on the issue, or to demonstrate why the release of information would result in a competitive disadvantage. This has real consequences not only for third-party payors, but also the individuals that they insure— premiums are a reflection of claims paid and if payors are not able to negotiate the most favorable terms, the insured individuals will pay higher premiums for their health care coverage.*

*Finally, the current rule allows the MHDO to “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.” However, the proposed rule permits the disclosure of actual negotiated reimbursement rates by allowing disclosure of the individual elements of the total price paid—the paid amount, co-pay, deductible, etc., are all Level I data. If it is the intent to allow such disclosure, we are strongly opposed to this provision; if it is not the intent to permit such disclosure, then the proposed rule should be amended accordingly.*

**Agency Response:** In the proposed rule we took the opportunity to clarify the ambiguity that we feel exists in the current data release rule specific to how the Agency defines data that has not been made available to the public and if made available may result in the Data Provider being placed in a competitive disadvantage, Section 2(31) Proprietary Data. Note: Data Provider is defined in Section 2(9) includes a health care facility, practitioner, health care claims processor or carrier....In the proposed rule we are explicitly state in the definition of Proprietary Data that the data sets we release will not include the charge data element. Prior to 2003 MHDO did release the charge data element 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 claims 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 facility. After much discussion the decision was made by the Agency that 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, health plans since 2003. All data requests are publically posted 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.

To address the issue of due process for data providers we are amending Section 10. In response to the issue of releasing financial information that comes from the claims data, the MHDO has been releasing the financial data elements associated with claims data (which includes the paid amount and the member share if applicable) for over ten years. The release of the financial data is necessary in order for the MHDO to fulfill its 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).

**Agency Action: Revise Section 10 (4) and Section 11 (1) as follows:**

For all data requests ~~that include Supplemental Data (APPENDIX C), Level II Data, or Level III Data,~~ the data providers or other interested parties may submit to the Executive Director comments related to the data request. To be considered, comments must be received by the Executive Director in writing or electronic notification no later than thirty business days after the initial posting of the data request on the MHDO web site. If the Executive Director determines that (a) the comments received are of significant importance to delay the release of ~~Supplemental Data or Level II Data~~ and/or (b) additional information is required from the requesting party to address the comments; then the ~~data for Supplemental or Level II requests~~ shall not be released until the additional information has been received from the requesting party and an additional review is conducted by the Executive Director or the MHDO Data Release Subcommittee, as applicable, to ensure that the requesting party conforms to all applicable requirements of this chapter.

Decisions of the Executive Director ~~regarding release of Level I Data which involve no Supplemental data to a data applicant,~~ denying the release of any data or data elements, directing the return or destruction of MHDO, or the modification of a document that contains or uses MHDO Data, are not reviewable. Neither the data applicant nor a data submitter can appeal these decisions. ~~Data released under this subsection may be released to the data applicant immediately provided the data applicant meet the requirements of these rules.~~

**Comment:** *In section 3(1)(C) and in several other places in the proposed rule, it states that decisions of the MHDO with respect the release of data are not reviewable. It is not clear to what review this is intended to apply. Such a prohibition on review is in violation of the Maine Administrative Procedure Act, which provides that “[e]xcept where a statute provides for direct review or review of a pro forma judicial decree by the Supreme Judicial Court or where judicial review is specifically precluded or the issues therein limited by statute, any person who is aggrieved by final agency action shall be entitled to judicial review thereof in the Superior Court in the manner provided by this subchapter.” 5 M.R.S.A. § 11001(1). The MHDO cannot, through rulemaking, supersede or eliminate the right to review under the Maine Administrative Procedure Act.*

**Agency Response:** PL 2013 Chapter 528 Section 22 MRSA Section 8 (7)(1)(4)(1).... Decisions of the organization or employees and subcommittees of the organization on data release are not reviewable. The intent of this provision is to prevent the MHDO from being ordered to release data. This provision is an exception to the Maine Administrative Procedure Act because it specifically precludes judicial review.

**Agency Action:** Revise the language in Section 10 (4) and Section 11 (1) as described in the Agency Action immediately above.

**Comment:** *Section 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(J) to provide that “As between MHDO and the data recipient, MHDO shall maintain ....” A similar change should be made to section 4(2)(C) as well.*

**Agency 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.

**Agency Action:** No further clarification needed.

**Comment:** *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.*

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

**Agency Action:** No further clarification needed.

**Comment:** We would suggest revising this section to clarify that it is the MHDO that is providing the choice/ Section 13(1)(A) could be amended as follows:

- A. Choice regarding disclosure of information: The MHDO shall provide the opportunity for a Any person to ~~may~~ choose to opt out and have their direct patient identifiers excluded from all subsequent Level III Data releases ~~by opting out.~~

**Comment:** We would further suggest that paragraph B be last and paragraphs C and D be re-lettered accordingly, the provisions governing the “opt out”, are followed by the process for doing so, with the ability to “opt in” at the end.

**Agency Response: Agree**

**Agency Action: Revise Section 13 as described below:**

- D. Choice regarding disclosure of information: The MHDO shall provide the opportunity for aAny person to ~~may~~ choose to opt out and have their direct patient identifiers excluded from all subsequent Level III Data releases. ~~by opting out.~~

~~E. A person who has chosen to have their direct patient identifiers excluded from Level III Data releases may choose to opt back in at any time.~~

~~F.E.~~ An individual that decides to opt out or opt back in is responsible for completing the MHDO Choice Disclosure Form available on the MHDO Public Website or by calling the MHDO and filling the form out telephonically. Individuals who opt out of a specific study will remain opted out of Level III Data releases unless they opt back in.

F. The MHDO will post all Level III Data requests on its publically accessible website. Individuals who want to opt out of a specific Level III Data release may do so by completing the MHDO Choice Disclosure Form no later than thirty business days after the initial posting of the data request on the MHDO web site. Individuals that do this will remain opted out of all subsequent Level III Data releases by MHDO unless they choose to opt back in.

G. A person who has chosen to have their direct patient identifiers excluded from Level III Data releases may choose to opt back in at any time.

**Comment:** *the classification of group number as Level II data potentially allows the cherry picking of small groups. This potential is recognized under the Maine Insurance Code, which does not require that small group experience information be released. Furthermore, it potentially allows an employer or other individual to identify an individual's claims or diagnosis. For example, if a group of 10 obtains there is only one 50 year old on the plan or only one individual with a high cost condition, it would be very easy for someone to determine the claims associated with that individual. We believe it would be advisable to limit the disclosure of this information to large groups, consistent with the provisions of the Insurance Code, and to use an MHDO Assigned Replacement Number or Code, rather than the actual group number.*

**Agency Response:** Today we limit the release of claims data that has been identified at the Payer Assigned Group ID Number to very large groups in an effort to minimize the risk of the identification of individual receiving health care services. In response to the last point the data release procedures described in Section 3 (3)(D) provide a level of protection where we do not feel it is necessary to add an additional step and create a replacement number of code for this data element.

**Agency Action:** Add language to Section 3 (3)(D) as follows:

In order for the MHDO to consider releasing a payer assigned group ID number the affected employer must have at least 500 covered employees on their health plan. The Data Applicant must obtain written authorization from the affected health plan and employer and/ or plan sponsor.

5. Anne Rogers submitted the following comment(s):

**Comment:** *Is it possible to add language to allow for the continued provision of de-identified and or aggregated substance abuse and psychiatric treatment data to Maine DHHS offices?*

**Agency Response:** The proposed rule does not prohibit the release of Level I or Level II substance abuse and psychiatric treatment data. This data is available consistent with how it is released today.

**Comment:** *Will the MOU between MHDO and MeCDC/DHHS need to include language in it to continue to allow MeCDC be the agent for DHHS and allow provision of the aggregate data to DHHS offices for purposes of Epi/Evaluation annual reports?*

**Agency Response:** The existing Memorandum of Understanding between the MHDO and DHHS

**will need to be updated to allow for the continued redistribution arrangement.**

**Comment:** *In Section 4.2.J (page 14) states all reports need to be provided to MHDO 20 days prior to publication. If we are continued to be allowed to receive MHDO data from Me CDC, will we need to get the information to Me CDC to send to MHDO or send directly to MHDO? Does this include regular annual reports where the information is just updated with the new year of data?*

**Agency Response:** All reports that use the MHDO data need to be sent directly to the MHDO.

**Agency Action:** No further clarification needed.

6. Andy Smith submitted the following comment(s):

**Comment:** *Will it be possible to maintain the existing DHHS-MHDO MOU where ME-CDC acts as a data redistribution agent under the new rules?*

**Agency Response:** The existing Memorandum of Understanding (MOU) between the MHDO and the DHHS needs to be revised and updated. The concept of the ME-CDC acting as a data redistribution agent is allowable under the proposed rule.

**Agency Action:** Clarify language in Section 3(3)(I) and add a new definition in Section 2 as follows:

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. **Redistributors of the MHDO data can use the MHDO data for inclusion in a larger composite database or reports that are publically released.**

**Redistributor. A "redistributor" means an entity that purchases MHDO data for inclusion in a larger composite database that is publicly released.**

**Comment:** *The current rule 120 exempts federal and state government from the requirement of providing any publications with MHDO data for their review at least 20 days prior (pp 14-15, 9(B)(2)(b)(ix and viii)). There does not appear to be any such exemption in the proposed rule (pg 14, 4.2.J.). Nor does there appear to be a provision to waive the requirement when there are multiple reports of a similar nature (pp 14, 9(B)(2)(b)(viii)). This will require that ME-CDC make a request every time new data or data updates are made to standard surveillance reports and the Maine Tracking Network. This will also require that ME-CDC establish a mechanism to ensure that US CDC abides by the same requirements for any data or reports submitted by ME-CDC to the US CDC. ME-CDC requests that the current provision exempting federal and state government from report approval requirements be maintained in the proposed rules.*

**Agency Response:** It is important for the MHDO and the public to understand how MHDO data is being used to produce meaningful analysis in pursuit of improved health and health care quality for Maine people. As such we are requesting that all publications with MHDO data be submitted to the MHDO in advance of the publication. Given the nature of the work of the ME-CDC as described above the logistics of adhering to this requirement are challenging. As part of updating the MOU between the MHDO and the Me-CDC the MHDO will work with the ME-CDC to find a solution regarding this issue that works for both parties.

**Agency Action:** No further clarification needed in the proposed rule.

**Comment:** *New data encryption requirements. (p. 12 – Section 3.G.) states: “MHDO Data recipients must demonstrate levels of security and privacy practices commensurate with health industry standards for PHI, and with data encrypted at rest and in transit. Data recipients must be able to demonstrate their ability to meet privacy and security requirements. Data releases will be made available to authorized users via an encrypted secure download process.” Does this mean that ME-CDC will have to encrypt the SQL-server database on which we store MHDO data and any derived data files that reside behind State of Maine secure firewall?*

**Agency Response:** MHDO data recipients must have a data security plan that is consistent with industry standards and best practice. The industry standard is that Protected Health Information is encrypted at rest unless the data recipient can meet the same level of protection through an alternative practice.

**Agency Action:** No further clarification needed in the proposed rule.

**Comment:** *ME-CDC recognizes that 22 §8714 provides the authority for MHDO to make decisions on data release regarding general public access non-reviewable. However, 22 §8715 establishes permitted use and disclosure to public health authorities, absent the language present under §8714. Furthermore, existing DHHS statutory authority under 22 §1692-B appears to require access to these data under certain conditions: “The Department of Health and Human Services must be given access to all confidential reports and records filed by physicians, hospitals or other private or public sector organizations, with all departments, agencies, commissions or boards of the State for the purpose of conducting investigations or evaluating the completeness or quality of data submitted to the department's disease surveillance programs. The department shall follow the data confidentiality requirements of the departments, agencies, commissions or boards of the State providing this information.”*

*ME-CDC therefore recommends that MHDO expand Section 9 to more fully recognize the ability of public health to access Level I, II, and III data.*

**Agency Response:** Section 9 does not need to be expanded as described above. Rather we will add a new provision to Section 3 of the proposed rule. The MOU and DUA will address access to Level I and Level II data files. Access to Level III data is defined in Section 9.

**Agency Action:** Add to Section 3: (4)(A) the following language:

*These rules may be modified to the minimum extent necessary to accommodate a memorandum of understanding and data use agreement with the Maine Center for Disease Control and Prevention (ME-CDC) for the ongoing release of Level I and Level II data to the ME-CDC for their purpose of conducting investigations or evaluating the completeness or quality of data submitted to the department of Health and Human Services Disease Surveillance programs.*

We request MHDO add the following data elements to the appropriate appendices:

**Hospital inpatient data**

- a. Date of birth for 90+ year olds – would be a Level II element
- b. Medicare Severity Diagnosis Related Group (MS-DRG) – would be a Level I element
- c. Medicare Severity Major Diagnostic Category (MS-MDC) – would be a Level I element
- d. All Payer Refined Diagnosis Related Group (APR-DRG) – would be a Level I element
- e. All Payer Refined Major Diagnostic Category (APR-MDC) – would be a Level I element
- f. Taxonomy code for attending provider – would be a Level II element
- g. Taxonomy code for secondary provider – would be a Level II element
- h. Name of secondary payer – would be a Level II element
- i. Name of tertiary payer – would be a Level II element
- j. City name – would be a Level II element

**Hospital outpatient data**

- k. Full date of service from – would be a Level II element
- l. Full date of service to – would be a Level II element
- m. Date of birth for 90+ year olds – would be a Level II element
- n. City (text version) – would be a Level II element
- o. State – would be a Level II element

**Agency Response:** All but one of the data elements listed above has been addressed in the technical corrections document that the agency submitted on 12/29/14. The one exception is the issue regarding date of birth for 90+ year olds. In an effort to minimize the potential identification of an individual 90 years or older date of birth will be suppressed if age is equal to or greater than 90 years old at time of service or eligibility in Level I and Level II date releases. In a Level III data release we will release date of birth for individuals 90 years and older.

**Comment:** *ME-CDC receives supplementary data tables for validation or translation of data fields. ME-CDC currently receives get tables for Hospital Information, translations tables for Source of Admission, Type of Admission, Race, Ethnicity, Revenue Codes, Health Planning Areas, Hospital Service Areas and sometimes MHDO has even shared the tables he references to assign Geocodes. These additional data elements were not listed as available under the proposed rules, but are necessary for both quality assurance checks and data translation and data querying.*

**Agency Response:** **The information in the supplementary data tables described above are definitions of national standard code sets that are available in the public domain. The MHDO will continue to include this information with our data releases.**

**Agency Action:** **No further clarification needed in the proposed rule.**

**Comment:** *p. 33, Appendix A.2: We recommend stating explicitly that E-codes will be released, perhaps by changing “Second through Eleventh Diagnoses Submitted” to “Second through Eleventh Diagnoses (or E-codes) Submitted.” Diagnoses and E-codes are both explicitly listed for Outpatient, but only diagnoses are currently listed for Inpatient.*

**Agency Response:** **One of the technical corrections made in the document submitted by the Agency on 12/19/14 was to consolidate all types of diagnosis codes into a general category of diagnosis codes. The MHDO will release all diagnosis codes received in the source data.**

**Agency Action:** **No further clarification needed in the proposed rule.**

**Comment:** *P 33, Appendix A2 Bullet: **Ancillary Revenue Code(s).** (Inpatient Only) This represents the revenue codes. Prior to 2012 we received 30 Codes. Beginning in 2012 the number increased to 50. It is critical to ME-CDC that these fields represent distinct codes. In other words the same code should not be represented twice. The reason for this is we use the Revenue Code field to know if there was an Emergency Department (ED) component.*

**Agency Response:** **The MHDO only releases distinct revenue codes. The reason why there was a rule change in 2012 to expand the number of revenue code from 30 to 50 was because 30 fields was not enough to report all distinct revenue codes.**

**Agency Action:** **No further clarification needed in the proposed rule.**

**Comment:** *p.32-34 and 42-43, Appendices A.2 and B.2: The hospital encounter data element lists in Appendix A.2 and B.2 do not always list the number of fields that will be provided for a particular element. The datasets should include all diagnosis and E-code fields received from*

*the hospitals (i.e., do not limit diagnoses/E-codes to the same number of fields MHDO has provided in the past if more fields are submitted by hospitals).*

**Agency Response:** One of the technical corrections made in the document submitted by the Agency on 12/19/14 was to consolidate all types of diagnosis codes into a general category of diagnosis codes. The MHDO will release all diagnosis codes received in the source data.

**Agency Action:** No further clarification needed in the proposed rule.

**Comment:** p. 8 -- 33. Public Data section: “publically assessable” should be “publically accessible”

**Agency Response:** Agree

**Agency Action:** Revise definition in Section 2. (33) as follows:

Public Data. “Public Data” is data that is available on the MHDO publically **assessable** **accessible** website as required by Title 22, Chapter 1683. Public data includes those parts of hospital Financial Data, described in Chapter 300, and Quality Data, described in Chapter 270 which are available on the MHDO publically accessible website.

**Comment:** p. 8 -- 34. Public Health Authority section: “Maine Centers for Disease Control and Prevention” should be “Maine Center for Disease Control and Prevention”

**Agency Response:** Agree

**Agency Action:** Revise definition in Section 2. (34) as follows:

Public Health Authority. “Public Health Authority” means a state or federal agency or authority that is responsible for public health matters as part of their mandate, such as those legally authorized to collect and or receive information for the purposes of preventing or controlling disease, injury or disability. For example the Maine Centers for Disease Control and Prevention, and the federal Centers for Disease Control and Prevention are Public Health Authorities.

**Comment:** p. 10 – Section 1.F: “Maine Centers for Disease Control” should be “Maine Center for Disease Control and Prevention”

**Agency Response:** Agree

**Agency Action:** Revise Section 3 (1)(F) as follows:

HIV Tests and status. Level III Data shall not be released, nor shall any data released by MHDO be used, to individually identify any person's HIV status, including the results of an HIV test, except to the Maine Centers for Disease Control on appropriate application and with a MHDO DUA, to fulfill its statutory duties under 22 M.R.S.A. Chapters 250 and 251. 5 M.R.S.A. §§ 19203 & 19203-D.

7. Karynlee Harrington submitted technical corrections as identified in the red-line version of the proposed rule that is attached.

DRAFT