Center for Health Information and Analysis
Regulation 957 CMR 5.00: Health Care Claims, Case Mix and Charge Data Release Procedures Effective July 19, 2013

INTRODUCTION

This regulation governs the procedures for releasing certain payer data, hospital case mix data and hospital charge data collected by the Center. The regulation applies to data collected for the Center's All Payer Claims Database (APCD) and the Acute Hospital Case Mix and Charge Data (Case Mix) Databases. The Center's goal is to allow access to reliable information to promote improvements in the health care system while implementing reasonable procedures to safeguard patient privacy and foster data confidentiality and security. The regulation requires all applicants requesting data to submit to a written application identifying the data sought and the purposes for which the data are sought. The regulation further requires all applicants to enter into a data use agreement (or an Inter-agency Service Agreement (ISA), if applicable) with the Center upon approval of the application prior to receiving requested data. The data use agreement (DUA) includes data privacy, confidentiality and security provisions to foster patient privacy and the confidentiality and security of the data being provided.

DISCUSSION

I. Background

On May 9, 2013, the Center proposed regulation 957 CMR 5.00: Health Care Claims, Case Mix and Charge Data Release Procedures. The Center conducted a public hearing on the proposed regulation on June 14, 2013, and public comments regarding the proposed regulation were allowed through June 24, 2013. Approximately ten individuals attended the public hearing, one of whom provided testimony on behalf of a health plan association. The Center received eight written comments (excluding duplicates and revised comments) regarding the proposed regulation and six written comments regarding the related proposed DUAs. The Center reviewed and considered the testimony provided at the public hearing together with the comments submitted in connection with this regulation. On July 2, 2013, the Center adopted a final revised regulation that addresses some of the issues and concerns raised in the testimony and comments provided on the proposed regulation. The Center also made revisions to the regulation to improve its organization and clarity. The final regulation is effective July 19, 2013.

II. Regulatory Provisions Addressed in Testimony and Comments

Direct Patient Identifiers

The regulation defines direct patient identifiers (DPIs) as personal information, 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. The proposed regulation contained a provision prohibiting the release of DPIs to applicants under Section 5.06 of the regulation.

Substance Abuse, Mental and Behavioral Health Information

The regulation defines Protected Health Information (PHI) as any individually identifiable health information (including any combination of data elements) that relates to the past, present, or future physical or mental health or condition of an individual; or the past, present or future payment for the provision of health care to an individual; and (a) identifies an individual, or (b) with respect to which

there is a reasonable basis to believe that the information can be used to identify an individual patient. Substance abuse, mental and behavioral health information that identifies or can be used to identify an individual constitutes PHI under the regulation and is subject to the additional federal, state and regulatory protections referenced therein.

Data Privacy, Confidentiality and Public Records Exemption
The regulation requires all applicants, upon approval of the applicant's application, to enter into a DUA (or ISA if applicable) with the Center. The DUA includes data privacy, confidentiality and security provisions to foster patient privacy and the confidentiality and security of the data being provided. The regulation also provides that data released thereunder are not a public record.

Data Release for Benchmarking and Administrative or Planning Purposes
The regulation allows the release of de-identified data to government agencies, payers, providers, provider organizations and researchers for the purpose of lowering total medical expenses, coordinating care, benchmarking, quality analysis and other research, administrative or planning purposes. Requests for de-identified data for any other uses, including commercial uses involving the resale or reuse of the data, are subject to additional regulatory requirements and restrictions. Under the regulation, "de-identified data" is defined as information that does not identify an individual patient and with respect to which there is no reasonable basis to believe the data can be used to identify an individual patient.

Commercial Use of Data
The regulation allows the release of data for commercial use subject to applicable requirements and restrictions. Applicants requesting data under Section 5.06 of the regulation must meet the public interest requirement stated therein. Data may be released for commercial use where the purpose of the requested data is in the public interest.

Antitrust Issues
The regulation grants the Executive Director of the Center discretion in determining whether certain data requests are in the public interest. That discretion includes the ability to consider whether approving a given data request is likely to have an anti-competitive effect. Those requests that are determined to be contrary to the public interest would be denied.

Data Release Methodology and Process
The regulation requires all applicants requesting data to submit a written application identifying the data sought and the purposes for which the data are sought. The regulation further requires all applicants to enter into a data use agreement (or ISA if applicable) with the Center upon approval of the application prior to receiving requested data.

The release procedures vary based on the kind of data requested and the nature of the applicant's organization:

- The regulation allows the release of de-identified data to government agencies, payers, providers, provider organizations and researchers for the purpose of lowering total medical expenses, coordinating care, benchmarking, quality analysis and other research, administrative or planning

purposes.

- The regulation also allows the release of patient identifiable data to payers, providers and provider organizations for the limited purpose of treatment and coordination of care and to government agencies, provided such data is limited to the minimum amount reasonably necessary to achieve the public purpose for which such data is sought.

- The regulation allows the release of Medicaid and Medicare data provided the applicant for such data demonstrates compliance with additional Medicaid and Medicare requirements regarding access to and use of such data.

- All other requests for data are subject to review by a Data Privacy Committee as well as a Data Release Committee and are further subject to the discretion and approval of the Executive Director. The Executive Director will approve an application if the Executive Director determines that the applicant has demonstrated that the purpose of the request is in the public interest, that the data sought are the minimum amount necessary to achieve the purpose of the study, that the applicant is qualified to undertake the study, and that the study poses no more than a minimal risk to individual privacy.

The Executive Director may also impose conditions on the use and disclosure of data released under this regulation.

Data Use Agreement
The regulation defines a data use agreement as document detailing a data recipient's commitments to data privacy and security, as well as restrictions on the disclosure and use of the data. The regulation requires all applicants to enter into a data use agreement (or ISA if applicable) with the Center upon approval of the application prior to receiving requested data. There are separate data use agreements for governmental and non-governmental applicants.

III. Analysis and Responses to Public Testimony and Comments
The Center reviewed and carefully considered the testimony provided at the public hearing together with all the comments submitted in connection with this regulation. Testimony and comments that raised major substantive issues are summarized below with the Center's response following immediately thereafter.

A. Direct Patient Identifiers (Sections 5.02, 5.06)

Comment: The Center received comments from five union branch offices. The union branch offices voiced concerns over the definition of "direct patient identifiers" and the regulatory provision prohibiting the release of such DPIs to applicants under Section 5.06 of the regulation. One branch office stated that the definition was too broad and recommended that it should spell out which exact values will be treated as DPIs and thus not subject to release. One branch office expressed opposition to including "5-digit zip code" as a DPI that is not subject to release. Another branch office similarly

expressed opposition to including "date of birth" as a DPI that is not subject to release and noted that issues on health care access, childhood immunizations and coverage gaps for seniors may require actual dates of birth and should thus be available to researchers able to demonstrate the need for such a data element. All the union branch offices strongly urged the release of 5-digit zip codes for researchers that require such information for studies on geographic health care disparities, income-based health care disparities, and other health care segregation issues.

Response: In response to the comments provided and the Center's goal of facilitating access to information to promote improvements in the health care system, the Center has removed the blanket prohibition on the release of DPIs to applicants under Section 5.06 of the regulation. Requests for DPIs under Section 5.06 of the regulation are subject to review by a Data Privacy Committee as well as a Data Release Committee and further subject to the discretion and approval of the Executive Director. Criteria for approval include a demonstration that the request is in the public interest, that the data sought are the minimum amount necessary to achieve the requestor's stated purpose, that the applicant is qualified to undertake the proposed study, and that the study poses no more than a minimal risk to individual privacy. The Executive Director may also impose conditions on the use and disclosure of data released under this regulation.

B. Substance Abuse, Mental and Behavioral Health Information (Sections 5.02)

Comment: The Center received comments from one health care insurer voicing concerns over substance abuse, mental health and behavioral health claims data being accessible to outside parties and also concerns over how such data would be identified and protected notwithstanding such conditions being included in the definition of PHI.

Response: Under the regulation, substance abuse, mental and behavioral health information that identifies or can be used to identify an individual constitutes PHI and is subject to federal, state and regulatory protections referenced in the regulation. The Center is preparing filters to safeguard such data from release.

C. Insurer Data Privacy, Confidentiality and Public Records Exemption (Sections 5.03 - 5.08 and DUAs)

Comment: The Center received comments from one health care insurer voicing concerns over the privacy, confidentiality and public records exemption status of insurer data. The insurer noted that unmasking payer identification in the APCD does not uphold the statutory requirement of insurer data privacy and confidentiality. The insurer further noted that insurer data privacy and confidentiality should be maintained at all times and not be contingent upon which government agency holds the data. Additionally, the insurer noted that M.G.L. c. 12C, § 10 grants a public records exemption for only insurer data and not for both insurer and provider data as provided under the regulation.

Response: The release of information regarding payer identification is in accordance with the directive of M.G.L. c. 12C to promote transparency. The regulation incorporates safeguards to protect the privacy and confidentiality of the data being released, including provisions in the governmental and non-governmental DUAs that limit the use, re-use, and disclosure of data containing "confidential data, personal data, or protected health information."

The regulation provides the same public records exemption protection for insurer data as the statute, and extending such protections to all data released under the regulation does not diminish or otherwise undermine those protections for insurer data. Indeed, M.G.L. c. 12C, § 10(e) clarifies that a statutory public records exemption afforded to insurer data applies unless the Center specifically provides otherwise. Further, the public records exemption protections afforded to all data released under the regulation are permissible under M.G.L. c. 12C, § 12 and the exemptions referenced in M.G.L. c. 4, § 7(26)(a) and (c) and also comply with state and federal data privacy laws.

D. Data Release for Benchmarking and Administrative or Planning Purposes (Section 5.02, 5.04 and 5.06)

Comment: The Center received comments from one health care insurer and one health plan association regarding the definition and scope of data release for "benchmarking" and "administrative or planning purposes." The health plan association proposed definitions for the terms "benchmarking" and "administrative or planning purposes." The proposed definition for "benchmarking" would require the use of "aggregated" data from at least 5 payers while the proposed definition for "administrative or planning purposes" would be limited in scope to "quality assessment and improvement" purposes. As for the insurer, it noted that reference to "other planning purposes" should be limited to and interpreted in the context of government agency requests for data and further noted that such reference should exclude commercial purposes.

Response: The meaning and scope of the terms "benchmarking" and "administrative or planning purposes" are sufficiently clear in both the statute and regulation and the context therein and also from common industry standards and practices. The regulation includes a provision allowing discretion in determining that these terms do not include purposes that the Executive Director of the Center determines are contrary to the public interest. The regulation provides in Section 5.04 that requests for de-identified data for any other uses, including commercial use involving the resale or reuse of the data shall be reviewed under Section 5.06 of the regulation which imposes a public interest requirement.

E. Commercial Use of Data (Section 5.06)

Comment: The Center received comments from one health care insurer recommending that data not be released for commercial use since such applicants are not government agencies, payers, providers, provider organizations or researchers as referenced in the statute and because commercial applications do not meet the public interest standard.

Response: The regulation allows the release of data for all requests that meet the requirements set forth in the regulation to allow access to reliable information to promote improvements in the health care system while implementing reasonable procedures to safeguard patient privacy and foster data confidentiality and security. Further, the list of data recipients referenced in the statute is neither an exhaustive or exclusive list. Applicants requesting data under Section 5.06 of the regulation and the purpose for such data, as described in an application, must meet the public interest requirement of the regulation. Data may be released to an applicant for commercial use, sale or other purpose that meets the public interest requirement so long as other regulatory requirements are met. Data requests under Section 5.06 of the regulation that fail to meet the public interest requirement will be denied.

F. Antitrust Issues (Sections 5.03-5.06)

Comment and Hearing Testimony: The Center received comments from one health care insurer and one health plan association voicing antitrust concerns over the release of certain proprietary and confidential data. The Center also received testimony at the public hearing from an official of the health plan association voicing the same concerns. The insurer noted that transparency goals should not impede competition and further noted that the release of certain proprietary data is not in the public interest and could result in harm to consumers and the marketplace. The health plan association similarly noted both in its comments and hearing testimony that making proprietary and highly sensitive pricing and payment information available could have an anti-competitive effect. In its hearing testimony, the health plan association official noted that the Center has flexibility in releasing certain plan or provider data in an identifiable or de-identified manner. The health plan association recommended in its comments that non-governmental applicants only be given access to such data subject to the condition that "that the release or use of the data will not facilitate collusion or anti-competitive conduct and is not expected to increase the cost of healthcare."

Response: Section 5.04 of the regulation clarifies that the acceptable purposes for requests for de-identified data from Payers, Providers, Provider Organizations and Researchers exclude purposes that CHIA determines are contrary to the public interest. Such excluded purposes could include purposes with anti-competitive effect.

Section 5.06 of the regulation allows the Executive Director of the Center discretion in determining whether certain data requests are in the public interest. The Executive Director may deny requests for data that are contrary to the public interest where available information indicates that the request is likely to have an anti-competitive effect. The Executive Director may also impose conditions on the use and disclosure of data released under the regulation.

G. Data Release Methodology and Process (Sections 5.03 – 5.08)

Comment: The Center received comments from one heath care data organization voicing concerns and recommendations regarding the regulation's data release methodology and procedures and related application process. The organization noted that the "data product and analysis audit" is burdensome and would discourage use of its data services and further noted that its role as a "member services organization" is not defined in the regulation or is relegated to the category of "all other requests" which is likewise burdensome to the organization. Additionally, the organization recommended: (1) that the regulation be tailored to the type of "requested data" rather than to the type of entity "requesting the data;" (2) that the regulation and related forms distinguish between releases of de-identified and masked data sets versus data sets that allow identification of a patient's PHI whereby the former is subject to less stringent protections while the latter is subject to more stringent protections; and (3) that the regulation allow a more streamlined application process that distinguishes between requests for DPH and PHI and those that do not request such data.

Response: The current regulatory methodology corresponds to the statute in terms of the entities entitled to get access to the data; the types of data that may be provided subject to applicable restrictions; and the purposes for which certain data may be provided to certain entities. In response to the

comments provided and in keeping with the Center's goal of facilitating access to information to promote improvements in the health care system, the Center has streamlined the process for de-identified data requests by creating a separate DUA for non-governmental entities requesting de-identified data. Finally, the audit provision described in the regulation is discretionary and would be conducted as warranted based upon the specifics of particular applications.

H. Data Use Agreement (Governmental and Non-governmental DUAs)

Comment: The Center received several comments from a number of entities regarding the governmental and non-governmental DUAs. One state agency recommended that agency contractors be allowed to "stand in" for the agency as the data recipient and also stressed the need for conflict checks to make sure contractors who render services to multiple employers have no relationship with a data source when accessing data. One health insurer recommended that contractors of state agencies be required to comply with HIPAA standards and that the prohibition on publishing data derived from 10 or fewer individuals or claims be strengthened to prohibit the publication of data derived from 100 or fewer claims or individuals. One health plan association voiced concerns over duplicative administrative costs and overly burdensome password and magnetic tape requirements. One health care data analytics organization noted that the data destruction provisions were too specific, restrictive and in some instances impractical and recommended a more neutral and comprehensive approach to data destruction such as that of the National Institute of Standards and Technology. Another health care data organization recommended that the regulation and related forms distinguish between releases of de-identified and masked data sets versus data sets that allow identification of a patient's PHI whereby the former is subject to less stringent protections while the latter is subject to more stringent protections. One union branch office raised issues regarding the requirement of a confidentiality agreement and the provision of executed copies of such agreements; the requirement of liability coverage for claims arising from the DUA; restrictions on access to and transfer of data; and the disclosure of vendor names with access to data.

Response: The DUAs contain data privacy, confidentiality and security provisions that are intended to accomplish the Center's goal of facilitating access to information to promote improvements in the health care system while implementing reasonable procedures to safeguard patient privacy and foster data confidentiality and security. The Center considers these provisions to be reasonable and appropriate measures. Further, in response to the comments provided, the Center has adopted the recommendation of requiring state agency contractors to comply with HIPAA standards and has revised the governmental DUA accordingly. The Center has also created a separate DUA for non-governmental entities requesting only de-identified data, which gives the requestor more leeway in the implementation of measures to safeguard the privacy and security of de-identified CHIA data

The DUAs retain the original provision prohibiting the publication of data derived from 10 or fewer individuals or claims, as this is in line with the CMS standard. (*See* CMS Data Use Agreement Form CMS-R-0235, p.4 at http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms-r-0235.pdf.) The DUAs retain the original data security and destruction provisions which are in compliance with M.G.L. c. 93H and 93I.

IV. Summary of Final Regulation Changes

The Center adopted a final revised regulation that addresses various concerns and issues raised in public hearing testimony and comments provided regarding the regulation. Among other changes, the Center (1) removed the blanket prohibition on the release of DPIs to applicants under Section 5.06; (2) created a separate non-governmental DUA for de-identified data requests with more flexible data security requirements; and (3) revised the governmental DUA to subject governmental contractors to HIPAA standards for data privacy and security. Further, in accordance with the regulation as clarified herein, the acceptable purposes for requests for de-identified data from Payers, Providers, Provider Organizations and Researchers exclude purposes that the Center determines are contrary to the public interest.

CONCLUSION

The final regulation, as amended, achieves the statutory directives of M.G. L. c. 12C and the Center's goal of allowing access to reliable information to promote improvements in the health care system while implementing reasonable procedures to safeguard patient privacy and foster data confidentiality and security.