MARYLAND HEALTH CARE COMMISSION

Analysis of Informal Public Comments and Staff Recommendations

COMAR 10.26.06:

Maryland Medical Care Data Base

& Data Collection;

and

Draft 2013 MCDB Submission Manual

October 17, 2013

I. Introduction

With the advent of health care reform, there is an increased need in the State of Maryland and nationally for detailed information on health care utilization, the relationship between health care utilization and health plan benefit design, and quality of care. In response to the need for more information and to support other State agencies, such as the Maryland Insurance Administration and the Maryland Health Benefit Exchange, Commission, staff has developed needed revisions to its data collection rules for the Maryland Medical Care Data Base (COMAR 10.25.06).

Commission staff has worked collaboratively with stakeholders to develop and review the proposed regulations. On April 15, 2013 payors were alerted of the need for changes and notified of upcoming opportunities to engage in the process. A plan for expansion of the MCDB, explaining the rationale for the changes, was distributed to payors on June 24, 2013 and reviewed at a meeting of payors held on June 26, 2013.

On September 13, 2013, Commission staff released draft MCDB regulations for informal public comment. Staff also sought comments on a draft 2013 MCDB Submission Manual. The informal comment period closed on October 4, 2013. Staff considered the written comments and also held meetings with various payors and organizations that requested meetings in response to staff's offer to discuss the draft MCDB regulations and draft 2013 Manual. After considering the informal public comments, staff has made changes to the regulations and will be making changes in both the 2013 and the 2014 MCDB Submission Manuals. Staff will discuss and seek Commission approval of changes to the Manuals at the Commission's November meeting. Written comments were received from the following organizations:

Alliance of Maryland Dental Plans (Alliance)
CareFirst BlueCross BlueShield of Maryland, Inc. (CareFirst)
Cigna
DentaQuest
Maryland Medical Assistance Program (Medicaid), Department of Health & Mental Hygiene
Maryland Hospital Association (MHA)
Mega Life and Health Insurance Company (Mega)
United Healthcare (United)

The remainder of this document provides a summary of the written informal comments received and staff's analysis and recommendations. A complete set of the written comments is attached in Part IV.

II. Summary and Analysis of Informal Public Comments – MCDB Regulations

Section .01 Scope and Purpose

Summary of Comments:

The Alliance of Maryland Dental Plans requests clarification whether Maryland residents covered under non-Maryland contracts are to be included in the reports submitted. In addition it asks whether administrators of plans for self-funded businesses are to be included. Cigna raises a question whether requiring reporting on self-insured plans would be a pre-emption of the ERISA law. Cigna notes that it has been voluntarily providing self-insured data in past submissions. The Maryland Hospital Association strongly supported the collection of self-insured data, characterizing the collection of such data as critical.

Staff Analysis and Recommendation:

In response to the question posed by the Alliance, the reports made by payors will include Maryland residents covered under non-Maryland contracts.

As noted by the MHA, having data on the self-insured market is essential to fully understanding health care costs, utilization, and quality in Maryland. Staff appreciates the cooperation of payors that, like Cigna, previously have voluntarily provided data regarding self-insured plans. Staff believes that requesting data from self-insured plans is not preempted by ERISA. Massachusetts, another state with a history of collecting such information in its all-payer claims database (APCD), also requests self-insured data and has asserted that requiring data submission for self-insured plans is not preempted by ERISA (http://www.mass.gov/chia/docs/g/chia-ab/1014.pdf). Staff notes that Maine, another state with an APCD, also collects data from all health plans, including self-insured plans and third party administrators.

Section .02 Definitions

Summary of Comments:

The Alliance of Maryland Dental Plans, CareFirst, DentaQuest, and United request clarification regarding in the definition of "general health benefit plan" in .02B. They note that, under the definition of "payor", only dental plans and vision plans sold on the Health Benefit Exchange are required to submit data to the MCDB. DentaQuest and the Alliance request clarification on the definition of "payors" that are required to submit data. In particular, they seek clarification on whether excepted benefits are intended to be included.

Staff Analysis and Recommendation:

Staff agrees with the need for clarification of the definition of "general health benefit plan" and recommends revision to the renumbered definition as follows (underline indicates new language):

- .02B(8)(d): A vision plan certified by the Maryland Health Benefit Exchange; or
- .02B(8)(e): A dental plan certified by the Maryland Health Benefit Exchange.

Staff understands the question regarding excepted benefits to be related to limited-scope dental or vision plans. As noted in the revised definition of "general health benefit plan," only dental or vision plans certified by, and sold on, the Maryland Health Benefit Exchange are required to report.

Section .03 Persons Designated to Provide Data to the Commission

Summary of Comments:

The Alliance of Maryland Dental Plans, DentaQuest, and United request clarification whether Third Party Administrators (TPAs), Pharmacy Benefit Managers (PBMs), Qualified Dental Plans (QDPs), and Qualified Vision Plans (QVPs) would be required to report separately when such reports will be contained in the submission of another payor.

Staff Analysis and Recommendation:

Staff agrees with the commenters that a payor whose data is contained in another payor's submission should not be required to submit data separately. To clarify this, staff recommends changing .03B as follows (underline indicates new language; ~~strikethrough~~ indicates deleted language):

- B. Data ~~Already~~ Otherwise Collected by the Commission from ~~Providers and~~ Payors or Providers.
  (1) A payor's reports are considered submitted to the Commission if they are contained within the submission of another payor.
  (2) For the purpose of supplementing the MCDB, the Commission may include information that the Commission has otherwise received regarding providers and services."

Section .04 Process for Collecting Data

Summary of Comments:

Medicaid notes that the MCDB will not contain complete information on its enrollees, given that only Medicaid Managed Care Organization (MCO) data and not fee-for-service (FFS) data is cited in .04C. Medicaid recommends inclusion of FFS data.

Staff Analysis and Recommendation:

Staff agrees that FFS data is necessary to get a complete picture of the services rendered to Medicaid enrollees. As discussed with Medicaid, staff's intent was that Medicaid would add FFS data to the MCO data and include its Eligibility Data Report and Provider Directory Report.

Staff recommends the following change to .04C to note that Medicaid will be providing additional data along with the MCO data:

- C. An MCO shall provide each required report to the Commission through the Maryland Medical Assistance Program ~~(Medicaid)~~, which will provide the MCO reports and related information to the Commission.

Section .05 Time Period for Submitting Data Reports

Summary of Comments:

United recommends that the Commission provide a testing period for new submitters in advance of the routine submission timeline in order to establish appropriate data protocols. Medicaid noted that it permits at least six months of run-out for encounter submission, and perhaps longer for certain inpatient and higher-end services and, thus, recommend a six month run-out. CareFirst and the Maryland Hospital Association suggests that the regulation should use claims paid in the reporting period, regardless of service date. CareFirst noted that the timing of the 2013 annual submission and the 2014 first quarter submission would present challenges. In addition, CareFirst indicated that it favors defining quarters based solely on the claim payment date, rather than on the date of service.

Staff Analysis and Recommendation:

Staff agrees with United that a testing period would be helpful in ensuring that new submitters correctly make submissions in accordance with the MCDB regulations and the MCDB Submission Manual. Subject to availability of funds, staff intends to explore testing opportunities for new submitters.

Staff agrees with the suggestions by CareFirst and MHA that, beginning with quarterly submission in 2014, the requirement not be based on services rendered in the quarter but, instead, be based on claims paid during the quarter, regardless of service date. Thus, beginning with 2014 quarterly reports, there would no longer be a need for a run-out period, and identifying claims for reporting would be simplified for payors. In addition to address the concern of the overlapping due dates for the 2013 annual and 2014 first quarter submissions, the 2014 Submission Manual will specify that the first and second quarter submission be submitted simultaneously by August 31, 2014. The deadline for the 2013 annual submission will remain as June 30, 2013. For these reasons, staff recommends the following changes to Section .05:

- A. For services rendered in calendar year 2013:
  (1) Only those reporting entities designated under Regulation .03A(1) shall submit to the Commission a complete set of the entity's data for that period in the form and format described in Regulations .07 - .14 of this chapter by June 30, 2014.
  (2) The submission shall consist of all claims for services provided in 2013 that are adjudicated between January 1, 2013 and April 30, 2014, four months after the end of the reporting period.

B. For services rendered in calendar year 2014 and thereafter, each reporting entity shall submit to the Commission a complete set of the entity's data for claims paid during each quarter in the form and manner described in Regulations .07 – .14 of this chapter within ~~4~~2 months of the last day in the applicable quarter, unless a less frequent submission is specified by the Commission, with notice to reporting entities that includes a dated posting on the Commission's website.

~~C. Each submission shall consist of all claims for services provided in the previous reporting period that are adjudicated between the first day of the reporting period for which the submission is due through three months after the end of that reporting period.~~

Section .06 Protection of Confidential Information

Summary of Comments:

United requests a clarification of the process by which a payor submits data to the State-Designated HIE for the creation of a Master Patient Index (MPI). United requests that, if carriers are expected to maintain this encrypted data, a timeline be specified and further details be given regarding the expected role of the carrier. Medicaid states that it must approve any release of Medicaid data and that such data releases are subject to approval by DHMH's IRB. Medicaid also suggests that the Commission should seek statutory changes that would permit the MHCC to collect patient identifying information for limited purposes. It notes that if the Commission had this ability, the burden on reporting entities would be reduced because the intermediate step of submitting data to the State-Designated HIE would be eliminated.

Staff Analysis and Recommendation:

Staff agrees that clarification is needed. There are different types of patient identifiers described: a payor-generated and encrypted patient identifier; a universally unique identifier (UUID) generated and encrypted using an algorithm provided by MHCC; and an MPI to be assigned by the state-designated Health Information Exchange, which is the Chesapeake Regional Information System for our Patients (CRISP). The payor-generated identifier has been reported in the past and will continue to be reported. The UUID has been reported in the past and will continue to be reported until the MPI is consistently reported. The MPI is expected to be reported in all later submissions.

The process for creating and reporting the MPI will be detailed in the 2014 MCDB Submission Manual. In brief, payors must submit limited demographic data to CRISP, who will attach MPI identifiers, and return the cross-walk with the payer-generated ID to the payors. Payors will then include the MPI in the Eligibility File submitted to MHCC. The timeline for these transactions will coincide with the submission timeline and will be detailed in the MCDB Submission Manual. In order to clarify the submission requirements regarding MPI, staff recommends the following changes to .06A(2)(b):

- (b) Beginning with 2014 submissions, direct each reporting entity to:
  (i) Provide ~~provide~~ selected data to the State-Designated HIE for the creation and encryption of a Master Patient Index; and

(ii) Include Master Patient Index identifiers received from the State-Designated HIE in its eligibility data report, as provided in Regulation .11.

Staff acknowledges the validity of Medicaid's concerns regarding its control over any requests for Medicaid data, including the need for approval by the DHMH IRB. Staff notes that COMAR 10.25.11.01, which is referenced in the draft regulation, permits the Commission to use other recognized IRBs to consider requests for encounter level data. The Commission will use the DHMH IRB for requests for Medicaid data. Staff recommends the following changes to Regulation .06C to acknowledge Medicaid's authority over the release of Medicaid data:

- C. Disclosure of Data for Research Use.
  To ensure that confidential or privileged patient information is kept confidential, prior to any disclosure of data that contains "directly or indirectly identifiable health information", as defined in HIPAA:
  (1) A ~~a~~ review shall be conducted by ~~the Commission's~~ an appropriate Institutional Review Board, as provided in COMAR 10.25.11;
  (2) The Maryland Medical Assistance Program (Medicaid) shall review and approve any request for the release of Medicaid data.

Regarding Medicaid's suggestion that statutory changes be sought that would permit the Commission to collect patient identifying information for limited purposes, Commission staff notes that the MHCC cannot currently collect these fields because of existing law, Health-General Article §19-133(d)(3). Commission staff believes that Medicaid's suggestion of a statutory amendment has merit.

Section .09 Provider Directory Report Submission

Summary of Comments:

United requests confirmation that Pharmacy Benefit Managers, who submit stand-alone pharmacy data, are not expected to submit a Provider Directory Report. Medicaid notes that it already submits a provider directory to CRISP.

Staff Analysis and Recommendation:

Staff confirms United's understanding of the regulation. Staff understands Medicaid's concern, but notes that the provider directory is required in the MCDB for appropriate patient attribution to practitioners. Staff recommends no changes.

Section .15 Report Submission Methods

Summary of Comments:

United requests that updates to the MCDB Submission Manual be limited to semiannual and that six months lead time be provided to make necessary changes.

Staff Analysis and Recommendation:

Staff expects that it will only be making annual updates to the Manual. While multiple changes are being made for the 2014 submissions, staff anticipates that any changes other than the annual update will concern incomplete or incorrect information in the Manual. Staff recommends the following changes to .15B to clarify this intention:

- B. The MCDB Data Submission Manual shall contain technical specifications, encryption algorithms, layouts, required reports, and definitions for each reporting entity.
  (1) The Commission shall provide an annual MCDB Submission Manual by November ~~15~~ 21 of each year to be used for the reporting periods in the subsequent year.
  (2) The Commission may ~~provide quarterly updates to~~ correct incomplete or erroneous information in the MCDB Submission Manual, as necessary ~~at least 3 months prior to each submission due date~~ and provide notice of each correction on the Commission website and by email to the contact persons designated by payors.
  (3) The Commission shall timely post the annual MCDB Data Submission Manual ~~and each update to the Manual~~ on the Commission website and provide notice in the Maryland Register.

Section .16 Request for an Extension of Time

Summary of Comments:

United requests that the possible extension time revert to the 60-day period in the current regulations, rather than change to 30 days. In addition, it is concerned with the requirement to show "extraordinary circumstances" to receive an extension.

Staff Analysis and Recommendation:

Staff recommends no change to the regulation. With the move to quarterly submissions, staff notes that the current possible 60-day extensions, while appropriate for annual submission, could result in a cascading impact on quarterly submissions. The requirement to show extraordinary circumstances justifying an extension means merely that the need for the extension should be caused by events outside the payor's control. Staff notes that the urgency for timely data for State priorities, as well as the quarterly submissions, requires a stricter standard.

Section .17 Request for an Annual Waiver or Format Modification.

Summary of Comments:

The Maryland Hospital Association raises concerns about the validity of data if waivers or format modifications are permitted. The MHA encourages strict adherence to the established reporting standards.

Staff Analysis and Recommendation:

Staff understands MHA's concern and expects to grant an annual waiver request or format modification request infrequently, in the case of a situation beyond the control of a payor. It may occasionally be necessary, albeit rarely, to grant request for an annual waiver of the submission of a data report or a format modification request. Staff notes that, in making a request for a waiver or format modification, the payor must detail extraordinary circumstances that lead it to make the request. Such requests can be expected due to the great variation across carriers in data platforms and the variety of products sold. Staff intends to insist on compliance with the regulations' reporting requirements except when necessary due to the reporting entity's inability to provide a report or to "submit values for a specific data element…."

Section .19 Summaries and Compilations

Summary of Comments:

United raise concerns about the potential use of MCDB data, especially payment rates to providers, for collusion or anti-competitive activities. While United supports more open information being available to consumers, it recommends a transparent and standardized data release policy that will account for these considerations. CareFirst concurs with this position. United proposes the addition of the following language to Regulation .19: "Any public disclosure or use of data made available to the public shall not facilitate collusion or anti-competitive conduce and is not expected to increase the cost of healthcare."

Staff Analysis and Recommendation:

Staff shares United and CareFirst's interest in protecting MCDB data and only releasing data for appropriate uses and to qualified users. The Commission has a long history of protecting confidential information, and has had a detailed review process for release of the MCDB data, including IRB review. Staff notes that a workgroup is planned to identify sensitive fields in MCDB data products. Payors will be invited to participate in this workgroup and inform the development of data products and data release policy. Because current draft .19 provides that such summaries and compilations be made "in compliance with all applicable federal and State law and regulations, staff concludes that the stated concerns regarding collusion or anti-competitive activities are addressed. For this reason, staff recommends no changes.

Other Comments

Comments regarding encounter payment amounts:

Medicaid notes that MCOs do not currently submit encounter payment amounts, but that this data will be available after the launch of MMIS 3, which is expected to be operational in 2015, at the earliest. In the interim, Medicaid will provide estimates of encounter payment amounts.

Medicaid would also like to be involved in any definition of reports that are relevant to the Medicaid data submission.

Staff Analysis and Recommendation:

Commission staff appreciates Medicaid's efforts to provide estimates in lieu of payments in advance of direct reporting of payments from MCOs in MMIS 3. Staff invites Medicaid to review and comment on the MCDB Submission Manual, which provides specifications for each of the existing data reports. Staff also notes that a pilot test to map Medicaid MCO data to MCDB data is underway. Medicaid will continue to be included in all MCDB workgroups.

Comments regarding the MCDB Submission Manual

Cigna is concerned that moving data specifications to the MCDB Submission Manual provides too broad an authority regarding policy making to Commission staff. Cigna fears that this may permit policy changes without adequate review of stakeholders.

Staff Analysis and Recommendation:

Staff appreciates Cigna's concern and notes that the Commission has a long history of engaging stakeholders in making policy changes. The changes recommended by staff to the MCDB regulations and Manual have been presented and discussed at Commission meetings, carrier meetings, and workgroup meetings over the last six months. The motivation behind moving data specifications solely to the submission manual is primarily a practical issue. As delivery and payment systems change, policy needs arise, or errors are found, it is burdensome to change regulations each time a modification to field specification is necessary. Staff will always engage all stakeholders whenever changes are made to the Manual, and will seek approval of the Commission before finalizing changes.

General Comments

Most commenters supported the overall goals of MCDB expansion and the need to revise regulations to permit such expansion. Several commenters specifically noted their appreciation of the opportunity to be involved in the process and expressed their hope to continue such engagement.

Staff Analysis:

Staff is appreciative of the active involvement of stakeholders and will continue to partner with them in the expansion of the MCDB.

III. Summary and Analysis of Informal Public Comments – Draft 2013 MCDB Submission Manual

Data Submission Documentation and Data Summary Worksheets

Summary of Comments:

CareFirst and United note that the documentation requirements create an additional administrative burden, which will be exacerbated by the move to quarterly reporting.

Staff Analysis and Recommendation:

Commission staff understands the concerns about administrative burdens. The goal of the documentation and worksheets is to ensure that the appropriate data is received and to support data cleaning and auditing. That said, the Commission is embarking on an effort to build an automated Extraction, Transfer, and Loading (ETL) system, wherein most of these documentation items will not be needed. Work on this effort will begin by July 2014. In the interim, staff has reviewed the documentation and worksheet items. Staff anticipates it will remove the following items from the required documentation:

Page 15: Professional Services File Control Total Verification – SOURCE COMPANY
Page 16-19: All tables to be removed
Page 22: National Drug Code (NDC)
Page 23: Institutional Services File Control Total Verification – TYPE OF FACILITY
Page 25: Institutional Services File – RECORD STATUS
Page 26-28: All tables to be removed
Page 29: Eligibility File Control Total Verification – POLICY TYPE
Page 30-37: All tables to be removed

All other data submission documentation and data summary worksheets will remain in place. Pending review, modifications of existing documentation and worksheets may be made. Staff hopes this substantial reduction in requested documentation tables will alleviate administrative burdens for payors.

New and Modified Field Specifications

Summary of Comments:

Mega Life and Health Insurance, Medicaid, and United note that their ability to report on certain fields (e.g., Assignment of Benefits, CPT II codes, Zip Code + 4, NPI) are dependent on whether providers submit such information, and whether these fields are part of their claims databases.

Staff Analysis and Recommendation:

Staff notes that Section .17B details the process for a format modification request, wherein providers may request variances for specific fields with a written request 30 days before the applicable submission date. Staff will review requests on a case-by-case basis, consistent with past submissions.

Professional Services Data Report

Summary of Comments:

DentaQuest and the Alliance of Maryland Dental Plans note that dental specific fields, such as tooth number or surface, are missing from the Professional Services Data Report.

Staff Analysis and Recommendation:

Dental Plans will not be required to report until 2014. For this reason, the draft 2013 Submission Manual circulated along with the draft regulations intentionally does not include the dental specific fields. The 2014 MCDB Submission Manual will include the Dental Data Report, which is a modified version of the Professional Services Data Report and will include dental specific fields. Staff will send the Dental Data Report to dental plans to provide feedback before publication of the 2014 Manual.

Race and Ethnicity Thresholds

Summary of Comments:

United requests that the threshold for Source of Enrollee Race/Ethnicity Information be reduced from 95% to 3%. It states that it currently has between 2-3% direct assignment of race and ethnicity for its commercial plans. CareFirst requests that there be no threshold on Race and Ethnicity data.

Staff Analysis and Recommendation:

Staff understands the concerns regarding thresholds regarding direct reporting of race and ethnicity. The draft 2013 MCDB Submission Manual has a threshold for the *source* of data and not for the race and ethnicity assignment itself. If race and ethnicity data is not available, a payor may report either that it did not ask the enrollee, or that the enrollee was asked but refused to report it. Staff recommends no changes to the threshold for the Source of Enrollee Race/Ethnicity Information field.

It should also be noted that the ability to conduct analysis of utilization, quality, and costs by race and ethnicity is a priority for the offices of the Governor and the Secretary of Health and Mental Hygiene. To that end, proactive efforts from carriers are needed to make progress. Staff will be convening a workgroup on race and ethnicity reporting to the MCDB on October 22, 2013 to which payors have been invited. Alternate options and strategies for improving

reporting, such as indirect race and ethnicity assignment, leveraging other data sources, and education programs, will be discussed.

Provider Directory Report

Summary of Comments:

United seeks clarification regarding reporting on out-of-state providers to enrollees included in the data submission. It proposes including information on all practitioners who provide services to eligible enrollees.

Staff Analysis and Recommendation:

Staff confirms that this is the intention of the section of the Manual. For out-of-state services, only practitioners who serve eligible enrollees need to be included in the data submission.

IV. Informal Comments Received

FUNK & BOLTON
ATTORNEYS AT LAW

A PROFESSIONAL ASSOCIATION
TWELFTH FLOOR
36 SOUTH CHARLES STREET
BALTIMORE, MARYLAND
21201-3111
PHONE: 410.659.7700
FAX: 410.659.7773
www.fblaw.com

DAVID M. FUNK (MD)
BRYAN D. BOLTON (MD, PA)
REN L. TUNDERMANN (MD)
CHARLES D. MACLEOD (MD)
LINDSEY A. RADER (MD)
DEREK B. YARMIS (MD, DC)
JEFFERSON L. BLOMQUIST (MD)
MICHAEL P. CUNNINGHAM (MD, DC)
JAMES F. TAYLOR (MD)
DONALD B. DAVIS, JR. (MD)
ERIC S. SCHUSTER (MD, DC, PA)
SCOTT R. JAMISON (MD, DC)
KAREN J. KRUGER (MD)
KIMBERLY Y. ROBINSON (MD)
MARY T. PORTER (MD, DC)
MICHAEL E. MCCABE, JR. (MD, DC, VA)
MICHAEL V. FORLINI (MD)
BRADLEY J. SWALLOW (MD, VA)
CYNTHIA L. MCCANN (MD)
SENIOR COUNSEL
PATRICK W. THOMAS (MD)
ASSOCIATES
KIMBERLY M. BENNETT (MD)
GORDON P. SMITH (MD)
ADAM R. GAZAILLE (MD)
MARIANNA M. JASIUKAITIS (MD, PA, DC)
OF COUNSEL
STEPHEN P. CARNEY (MD)
RONALD L. SOUDERS (PA, DC)

October 4, 2013

Srinivas Sridhara
Acting Chief, Cost and Quality Analysis
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Draft Medical Cost Data Base and Data Collection Regulations

Dear Mr. Sridhara:

On behalf of the Alliance of Maryland Dental Plans, thank you for the opportunity to comment on the Commission's draft Maryland Medical Cost Data Base and Data Collection regulations. The Alliance represents many of Maryland's dental insurers and dental plan organizations. We have reviewed the draft regulations and offer the following comments.

Comment #1- Scope of the Regulations

Please clarify the scope of the regulations with respect to out of state plans and self funded plans. Regulation .01 indicates that they apply to "health care services provided under a Maryland contract or to Maryland residents." A Maryland resident may not be covered by a Maryland contract. Do the regulations require reporting on an health services provided to an individual who is covered by a contract situsued in another state but administered by a Maryland carrier or Third Parry Administrator? Additionally, do the regulations apply to self-funded business administered by a Third Party Administrator who is registered with the State? In clarifying the scope of reporting for Third Parry Administrators, it would also be helpful to clarify when a Third Party Administrator is not required to report because the data has been separately reported by another entity.

Comment #2- Regulation .02 Definitions

There are a few definitions that we believe require revision and clarification. Specifically, the definition of "general health benefit plan" includes dental and vision plans within its definition. It is our understanding that the regulation is intended to only capture data from qualified dental plans and qualified vision plans. If that is in fact the case, the definition of "general health benefit plan" is overbroad. Additionally, the definition of "Payor" does not encompass all dental benefit providers as it does not include dental plan organizations. It is not clear if the exclusion of dental plan organizations is intention or if it is an oversight. Further, if the intention is not to include HIPAA excepted benefits within the reporting, the use of the term "health insurance" in the definition of "Payor" may need to be revised. Generally speaking, the term health insurance is a broad term and

includes products such as dental, vision, disability, specified disease within its parameters. These products are not typically included in the reporting under claims payment databases and do not seem to be the intended targets of the reporting under these regulations.

Comment #3- Regulation .03 Persons Designated to Provide Data to the Commission

As previously noted, we understand the intention of the regulation to be to only include those dental and vision benefits that are provided through qualified dental plans and qualified vision plans on the Maryland Health Benefit Exchange. If this is true, we believe that the language in Regulation .03 should be revised to better reflect this intended scope. As written today, based on the definition of "general health benefit plan," all dental and vision plans seem to fall within the reporting requirements.

Comment #4- Professional Services Submission Data Report

The Professional Services submission does not appear to account for tooth number or surface. It is common to have the same procedure done on multiple teeth in the same encounter. Without collecting this information it is possible these services would be seen as duplicates to anyone reviewing the submitted data. We believe that appropriate changes to reflect tooth number or surface should be made.

Again, thank you the opportunity to provide comments. Should you have any questions on these comments, please do not hesitate to contact me.

Very truly yours,

Kimberly Y. Robinson

Maria Harris Tildon
Senior Vice President
Public Policy and Community Affairs

CareFirst BlueCross BlueShield
1501 S. Clinton Street, Suite 700
Baltimore, MD 21224-5744
Tel. 410-605-2591
Fax 410-781-7642

CareFirst

October 9, 2013

VIA EMAIL (srinivas.sridhara@maryland.gov)
Srinivas Sridaha
Acting Chief, Cost and Quality Analysis
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Dear Mr. Sridhara:

I write on behalf of CareFirst BlueCross Blue Shield ("CareFirst") and in response to the Maryland Health Care Commission's ("MHCC") proposed regulations Subtitle 10, Chapter 25 Maryland Medical Care Data Base and Data Collection and 2013 draft Submission Manual circulated for informal public comments. CareFirst appreciates the opportunity to provide feedback to the MHCC on some of the operational concerns CareFirst has with the proposed regulations. As you are aware, Ben Steffen agreed that CareFirst could first discuss its concerns and thoughts on the proposed regulations with MHCC staff prior to submitting written comments even if that delayed the submission of comments to the MHCC. CareFirst and MHCC staff spoke on October 8, 2013 and this letter summarizes the concerns raised during that conversation.

1. Race/Ethnicity Data. The 2013 draft Submission Manual provides for a threshold of 95% for the Source of Enrollee Race/Ethnicity Information. CareFirst appreciates the MHCC's and the State's efforts to focus on health disparities in the State and to utilize data to foster policy discussions on how to address such disparities. However, as consumers are not required to and cannot be compelled to report their race/ethnicity when applying for health insurance, CareFirst believes such a high reporting threshold is not only impractical but infeasible. We therefore appreciate the MHCC clarifying during our conversation that the MHCC does not interpret the threshold to be a requirement on a carrier to report the race/ethnicity of 95% of its enrollees but merely report data in the race/ethnicity field 95% of the time where such data could reflect an enrollee's race/ethnicity, that such information is unknown, or that the enrollee refused to provide the information.

Nevertheless, as the State moves to encourage carriers to indirectly assign an enrollee's race/ethnicity where it has not been provided, CareFirst recommends that the MHCC develop indirect assignment algorithms that can be uniformly applied across carriers to ensure consistency in reporting.

2. Reporting Frequency. Proposed regulation .05B would require carriers to quarterly submit to the MHCC a complete set of the carriers' data. As CareFirst expressed yesterday to the MHCC, quarterly reports pose a great resource challenge particularly where the data MHCC requests be submitted may be changed throughout the year. As CareFirst requires a minimum of 120 days' prior notice of any changes in the data to be provided to operationalize the requirement.

During our call, the MHCC acknowledged carriers' programming and operational concerns in changing reporting requirements. CareFirst understood the MHCC as confirming that it will not change the data reporting requirements more frequently than annually. CareFirst also understood that the MHCC would be modifying the reporting requirement from the current paid and incurred methodology to only a paid methodology. If these understandings are correct, CareFirst believes a quarterly report is feasible. If these understandings are incorrect, CareFirst has strong objections to the new requirement and recommends that data reports be submitted to the MHCC semi-annually rather than quarterly.

3. Manual/Worksheets. We appreciate the MHCC sharing on the call that it intends to remove certain portions of the existing worksheets that are antiquated or cumbersome for carriers to fill out. Nevertheless, CareFirst is concerned that future additions or changes to the Submission Manual or required worksheets may be burdensome or unnecessary. CareFirst therefore recommends that the MHCC establish a formal carrier engagement process prior to any changes to the Manual or worksheet requirements. Carrier involvement in the Manual and worksheet requirements is particularly important if the Maryland Insurance Administration is to use worksheets and data reports for rate setting purposes.

4. Implementation Date. A move from an annual submission to a transitional semi-annual submission to ultimately a quarterly submission may be feasible if carriers understand the timeline the MHCC seeks such transition to take place in. Absent a clear timeline, however, CareFirst is concerned about its ability to timely comply with deadlines it is not clearly aware of and the utility of such data to the MHCC. For example, the 2013 annual report is due to the MHCC on June 30, 2014. If CareFirst has to submit a quarterly report to the MHCC beginning in 2014, it would submit the Q1 2014 report by May 31, 2014, before the annual 2013 report is due. CareFirst therefore recommends that the MHCC include in the final regulations a timeline detailing the date by which a carrier must submit a report and the period the report covers. This will facilitate carriers' compliance with the reporting requirements and a thoughtful transition plan.

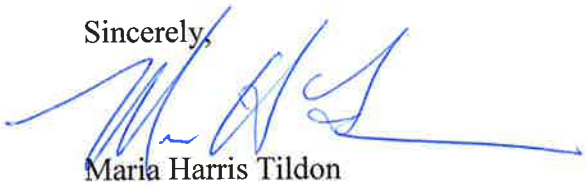
5. Dental and Vision Plans. Proposed regulation .02B(9) defines a "general health benefit plan" to include a vision plan or a dental plan. The MHCC clarified on our call, however, that the reporting requirements only apply to (a) standalone qualified vision or dental plans sold on the Maryland Health Benefit Exchange or (b) embedded dental or vision benefits in medical plans sold on- or off-Exchange. We recommend that this definition be modified to clarify that the reporting does not apply to off-Exchange standalone dental or vision plans.

6. Summaries and Compilations. CareFirst is concerned that the summaries and compilations the MHCC develops under proposed regulation .19 could be manipulated to reveal confidential and proprietary information about individual carrier rates with providers to carriers'

detriment. CareFirst recommends that regulation .19 be modified to expressly provide at the end that "Any such public-use data, summaries, and compilations shall be developed to prevent and prohibit reverse engineering, decompiling, decoding, decrypting, disassembling, or in any way derive carrier specific rating information."

Thank you for the opportunity to comment on the above regulations. If you have any questions, please feel free to contact me.

Sincerely,



Maria Harris Tildon

Patrick M. Gillespie
Director,
State Government Affairs

Law & Public Affairs

VIA ELECTRONIC MAIL

October 4, 2013

499 Washington Boulevard
Jersey City, New Jersey 07310
Tel 201-533-4538
Fax 860-298-2395
patrick.gillespie@cigna.com

The Honorable Srinivas Sridhara
Acting Chief,
Cost and Quality Analysis
Maryland Health Care Commission
4160 Patterson Avenue,
Baltimore, Maryland 21215

Dear Chief Sridhara:

Thank you for the opportunity to comment on the draft rules cited as COMAR 10.25.06 regarding "Maryland Medical Care Data Base and Data Collection." Cigna has concerns and believes that the policy issues presented in this document are significant enough to warrant a delay in publishing these proposed rules until there has been opportunity to discuss further with affected insurance carriers.

Cigna is dedicated to helping the people we serve improve their health, well being and financial security. Cigna offers products and services under the Connecticut General Life Insurance Company (CGLIC) or the Cigna Health and Life Insurance Company (CHLIC). Cigna-HealthSpring, formerly Bravo Health, also offers a variety of Medicare Advantage related products. All of these Cigna companies proudly serve our Maryland customers by providing health care solutions to meet their unique needs.

In general, All Payer Claims Database systems impose a significant administrative burden on carriers when there is increased pressure on carriers to reduce administrative costs. Unique programs in each state, with vastly different reporting requirements, create added challenges for national carriers like Cigna who operate claim platforms across multiple states.

In particular, Cigna is concerned about the construct of the draft rule and interaction with the technical manual. These draft rules would permit the Commission to impose ever more significant reporting requirements and other broad policy changes merely by revising a technical manual. The technical manual should be used solely to provide guidance to implement policies adopted under Maryland's administrative procedure laws. It is entirely inappropriate to use revisions to a technical manual as a vehicle for any policy changes.

Moreover, Cigna is concerned about how these proposed changes would impact Cigna customers for whom Cigna provides Administrative Services Only. The proposed scope of these rules would require including these plans which are governed by federal ERISA laws. While Cigna currently provides claims data on a voluntary basis, the additional requirements contemplated in these rules could undermine the pre-emption of state regulation of these ERISA plans.

While the foregoing issues are major, there are a host of other important issues presented in these draft rules. So, rather than provide an exhaustive list here, Cigna requests a meeting with the Commission to discuss and present our concerns. Cigna also requests that the Commission convene an informal working group of insurance carriers to review the draft rules prior to the publication of a rule proposal. Cigna representatives would be willing to serve on such an informal working group.

Thank you for the opportunity to comment on these issues. If you have any questions or desire additional information please do not hesitate to contact me.

With every best regard, I am

Sincerely,

Patrick M. Gillespie
Director,
State Government Affairs

CC: Julia Huggins, President and GM
Bryson Popham

DentaQuest

October 4, 2013

Srinivas Sridhara
Acting Chief, Cost and Quality Analysis
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Comments on COMAR 10.25.06: MARYLAND MEDICAL CARE DATA BASE AND DATA COLLECTION

Dear Mr. Sridhara:

On behalf of DentaQuest, I write in response to the call for public comment related to COMAR 10.24.06: Maryland Medical Care Data Base and Data Collection. DentaQuest is a dental benefits administrator serving more than 700,000 Marylanders. DentaQuest administers the state Medicaid dental program in addition to offering commercial dental plans via the Maryland health benefits exchange and directly to Maryland individuals and businesses.

Our team reviewed the reporting requirements contained in COMAR 10.25.06: Maryland Medical Care Data Base and Data Collection and identified the following issues for your consideration:

- Clarify definitions of "general health benefit plan" and "payor". Both definitions would be applicable to dental plans but it is unclear if the intent is to include only a Qualified Dental Plan (QDP) or and whether or not the regulation meant to pull in a fee-for-service or dental plan organization. As currently written all lines of dental plans are pulled into these definitions.

  Similarly, in section .03, a "payor" is required to provide data to the Commission. This would generally apply to non-exchange entities and normally excludes excepted benefits but again, under the current definition of "payor" excepted benefits would be pulled into this provision. We will need clarification as to whether or not excepted benefits were intended to be pulled into these data requirements.

- Clarification on TPA insured business. The language of the regulation suggests that TPAs are impacted for insured business that is not otherwise reported by a carrier providing data to MHCC. However, this is not explicit. Please provide clarification regarding required reporting for TPAs and the scope of the regulation with regard to the self-funded market.

- The Professional Services submission does not appear to account for tooth number or surface. It is common to have the same procedure done on multiple teeth in the same encounter. Without collecting this information it is possible these services would be seen as duplicates to anyone reviewing the submitted data.

- Universally Unique Identifier (UUID). We are unable to access details about the UUID encryption software documentation, source code, and executables. Without details we cannot fully comment on potential concerns related to Security and Compliance.

Thank you for the opportunity to provide comment. Please do not hesitate to contact me with any questions at kristin.laroche@improvingoralhealth.com or 617-886-1458.

Sincerely,

Kristin LaRoche
Manager, Government Affairs & Policy

STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

October 4, 2013

Srinivas Sridhara, PhD.
Acting Chief, Cost and Quality Analysis
Maryland Health Care Commission
4160 Patterson Ave.
Baltimore, MD 21215

Subject: Comments on Draft COMAR 10.25.06: Maryland Medical Care Data Base and Data Collection

Dear Dr. Sridhara:

The Maryland Medicaid Program respectfully submits this letter of comment on the draft regulations issued by the Maryland Health Care Commission (MHCC) on September 13, 2013.

Master Patient Index Encryption

The Medicaid Program has an overarching concern about the requirement in 10.25.06.06A to submit data to the Health Information Exchange (HIE) for the creation and encryption of a Master Patient Index. MHCC advises that it does not have the statutory authority to request patient identifying information because of Health General Article §19-133(d)(3) (requiring that certain health records be filed "in a manner that does not disclose the identity of the person protected"). But MHCC is tasked under the Centers for Medicare and Medicaid Services Qualified Entity Program with communicating with doctors about their own patients and how their patient data is being used to calculate physician performance measures. When it does so, MHCC will use the HIE's Master Patient Index that masks patient names with an encryption code. To examine information relating to their patient, therefore, the doctor must decipher the code in order to obtain the necessary information, which is a significant burden. The encryption process is proposed merely as a work-around for the above statutory limitation. Accordingly, we recommend that MHCC work on a statutory change that permits MHCC to collect patient identifying information for limited purposes. This would reduce the administrative burden on reporting entities by eliminating the intermediate step of submitting data to the HIE. This recommendation would also improve the Medical Care Data Base, increase MHCC's reporting capabilities, and facilitate physician use of data regarding their own patients.

Run-Out for Encounter Submission

10.25.06.05B requires each reporting entity to submit a complete set of data for each quarter within four months of the last day of the applicable quarter, unless a less frequent submission is specified by MHCC. The Medicaid Program typically allows at least six months of run-out for encounter submission before considering the data complete. Submission of encounter data for inpatient and higher-end services may take even longer than six months. If MHCC needs the data to be as complete as possible, we recommend extending the requirement to at least six months.

Institutional Review Board

10.25.06.06C requires the MHCC Institutional Review Board to review requests for the disclosure of patient information. The Medicaid Program is the custodian of and charged with safeguarding Medicaid information. Accordingly, the Medicaid Program must approve the release of any such information to third parties. We require that the Department of Health and Mental Hygiene Institutional Review Board approve all third party requests for Medicaid patient information. This is similar to Medicare requirements. This must be reflected in the regulations.

Carve-Out Services

The draft regulations designate Medicaid managed care organizations (MCOs) as reporting entities. It should be noted that MCO reporting would not capture services that are carved out of the MCO benefit package and offered on a fee-for-service (FFS) basis. Carve-out services include: specialty mental health services, dental services, therapy services for children, personal care services, long-term care services after the first 30 days of care, certain HIV/AIDS services, and HIV/AIDS and mental health prescriptions. Substance abuse services will also be carved out in the future. Therefore, comparisons between Medicaid and commercial plans may not be possible using the Medical Care Data Base as proposed.

Provider Directory Report

10.25.06.04B(3) requires reporting entities to submit provider directory reports. These submissions appear to duplicate the reports that the Medicaid Program is already submitting to CRISP.

Encounter Payments

The MCOs currently do not submit payment amounts with their encounters. The Medicaid Program is in the process of procuring the Medicaid Management Information System 3 (MMIS3). It is anticipated that this new system will collect encounter payments. The MMIS3, however, will not be operational until at least 2015. Until the MMIS3 is operational, we can work with MHCC to provide estimated prices for the MCO encounters.

Medical Care Data Base Submission Manual

10.25.06.07 through 14 direct reporting entities to submit data in the form and manner specified in the annual Medical Care Data Base Submission Manual. The Medicaid Program would like to

be included in the discussions on the development of this manual related to MCO submission requirements, such as benefit design reporting.

We thank you for the opportunity to comment at this time and appreciate your consideration of these comments. Please do not hesitate to contact me if you have any questions.

Sincerely,

Tricia Roddy

Tricia Roddy
Director, Planning Administration
Health Care Financing

cc: Charles J. Milligan, Jr.

Maryland
Hospital Association

MHA
6820 Deerpath Road
Elkridge, Maryland 21075-6234
Tel: 410-379-6200
Fax: 410-379-8239

October 4, 2013

Srinivas Sridhara
Acting Chief, Cost and Quality Analysis
Maryland Health Care Commission
41060 Patterson Avenue
Baltimore, MD 21215

RE: COMAR 10.25.06 Maryland Medical Care Data Base and Data Collection

Dear Mr. Sridhara:

On behalf of our 66 member hospitals, the Maryland Hospital Association (MHA) appreciates the opportunity to provide informal comments on the draft regulatory changes to COMAR 10.25.06 Maryland Medical Care Data Base (MCDB) and Data Collection. We support the MHCC's plans to make the data base more complete and more current. Overall we are pleased with the language but would like to recommend several revisions that would ensure all possible data resources are identified, clarify the data submission requirements, and strengthen payor compliance.

We are pleased to see that the proposed language will require reporting by payors that exceed 1,000 total covered lives, as opposed to the existing policy, which only requires those payors with more than $1 million in health insurance premium collections to report. It is also reassuring to see Medicaid MCOs included in the reporting requirements. However, it is unclear whether Medicaid fee-for-service data will be also collected. Additionally, the language is silent on whether self insured health plans will be required to submit data. In 2010, 33 percent of Maryland employers offered self insured plans, which enrolled 62.5 percent of employed Marylanders.[1] With such a high rate of Marylanders enrolled in self insured plans, it is critical that the data base include data from self insured plans.

We are also supportive of the change in the reporting timeline. By requiring quarterly data submissions, beginning in calendar year 2014, the database will more timely and useful as the state and providers seek to better understand healthcare cost and utilization. However, we would like to understand why only claims with dates of service from the previous period are required to be submitted. We would like to suggest that the language in section .05 be revised to read that the submission should consist of claims for services provided <u>in a prior</u> reporting period, rather than the previous reporting period, thus all the data is based on adjudicated claims regardless of when the service is provided.

[1] Spotlight on Maryland: A Profile of Maryland's Self-Insured Small Group Health Insurance Market, Maryland Health Care Commission, Center for Information Services and Analysis, May 2012.

Finally, we are concerned that the language in section .17, Request for an Annual Waiver or Format Modification, could be used to needlessly alter data submissions. It is critical that the MCDB contain consistent and valid data. Giving payors an opportunity to change the submission format jeopardizes the validity of the data contained in the MCDB. We would recommend that language in this particular section be strengthened to prevent data format modifications.

Again, thank you for the opportunity to comment on the proposed regulatory changes. If you have any questions, I can be reached at 410-540-5081.

Sincerely,

Anne Hubbard
Assistant Vice President, Financial Policy & Advocacy

FW: COMAR 10.24.06: Maryland Medical Care Data Base and Data Collection
StateReporting NonFinancial <StateReportingNonFin@healthmarkets.com> Thu, Oct 3, 2013 at 10:57 AM
To: "srinivas.sridhara@maryland.gov" <srinivas.sridhara@maryland.gov>
Cc: "DeTuro, Virginia" <virginia.deturo@healthmarkets.com>, "Robledo, AnaLisa" <analisa.robledo@healthmarkets.com>, "Sharp, Courtney" <courtney.sharp@healthmarkets.com>

Hello,

We have reviewed the draft regulations and Data Base Submission Manual and will comply with the quarterly request for the data submission.

If the providers will provide us with the information for the following categories we will be able to comply. The 4 digit add-on to the zip code is not always included from the members or the providers.

- New! The **CPT Category II** codes (Current Procedure Terminology II) field has been added to the Professional Services file. The CPT Category II codes will facilitate data collection about the quality of care rendered and for purposes of performance measurement.

- New! The **Diagnosis Code Indicator** field has been added to the Professional Services file. This field indicates the volume of the International Classification of Diseases, Clinical Modification system used in assigning codes to diagnoses.

- Modified! The **Patient/Enrollee Zip Code** field on the Professional Services, Pharmacy, Institutional Services, and Eligibility files has been expanded to include the 5-digit US Postal Service code plus the 4-digit add-on code and hyphen (e.g., 21215-2299).

- Modified! The **Service Location Zip Code** field on the Professional Services file and **Pharmacy Zip Code** field on the Pharmacy file have been expanded to include the 5-digit US Postal Service code plus the 4-digit add-on code and hyphen (e.g., 21215-2299).

- Modified! The **Place of Service** field on the Professional Services file has been updated to include **"Place of Employment-Worksite"** (code #18). This value aligns the MCDB categories with the CMS Place of Service code set.

We will need to do further research for these categories:

- New! The **Revenue Codes** field has been added to the Institutional Services file. Please provide the codes used to identify specific service, location, accommodation and/or ancillary charges. This field will improve identification of services provided in hospitals, for use in practitioner performance measurement system, and for pricing of procedures and treatment of chronic conditions.

- Modified! A new value has been added to the **Participating Provider Status** flag on the Professional Services file. **"No network for this plan"** (code #9) is an additional response option.

Please let us know if you have any questions or concerns.

Regards,

Tyrah Rodriguez
Regulatory Affairs Analyst II
Corporate Compliance
HealthMarkets®

9151 Boulevard 26 • North Richland Hills • TX 76180

P (817) 255-3204 • **F** (817) 255-8125
Tyrah.Rodriguez@HealthMarkets.com • www.HealthMarkets.com

UnitedHealthcare®
A UnitedHealth Group Company

Colleen C. Cohan
Associate General Counsel
Legal & Regulatory Affairs
800 King Farm Blvd, Suite 600
Rockville, MD 20850
Tel: (240) 632-8109

October 4, 2013

Srinivas Sridhara
Acting Chief, Cost and Quality Analysis
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

Re: Draft MCDB Regulation and Draft 2013 MCDB Submission Manual

Dear Mr. Sridhara,

On behalf of UnitedHealthcare and its affiliated companies, we appreciate the opportunity to comment on the draft MCDB regulations and draft 2013 MCDB Submission Manual. We further appreciate you and other members of the Commission staff taking the time on October 1, 2013 to speak with us regarding questions and concerns we have regarding both documents.

Draft MCDB Regulation Comments

Comment 1: Section .02 Definition of General Health Benefit Plan

As we discussed during our October 1, 2013 conference call, we understand that the definition of General health benefit plan does not include basic vision plans nor does it include dental plans except for those sold on the Exchange. We respectfully request that those clarifications be included in the definition of General health benefit plan.

Comment 2: Section .05 Timeframe for Submitting Data Reports

Section .05 Timeframe for Submitting Data Reports does not include a notation regarding test data submission for entities that become subject to the regulation after its initial implementation. We ask that the State include language in the regulation outlining the timing of test and production data similar to the following:

> Reporting entities that become subject to this regulation after January 15, 1996 shall submit to the Commission one month of eligibility, provider, medical claim and pharmacy claim data for determining compliance with the standards for data submission no later than 180 days after the first date of becoming subject to the regulation. Within 90 days of the Commission's acceptance of the test files, Reporting entities will submit historical data which will encompass the month they first became subject to the regulation through the current quarter.

Comment 3: Section .06 A – Filing Data Using Encryption

We ask that the Commission discuss with the reporting entities its planned process for directing each reporting entity to provide selected data to the State-Designated HIE for the creation and encryption of a Master Patient Index (MPI). We want to confirm whether or not reporting entities will be expected to receive, maintain and then submit information from the MPI regarding its respective enrollee. If this is the case, we will want to work with the Commission in outlining appropriate timeframes for the receipt and submission of data from the MPI. An example of appropriate timeframes are fifteen days for the vendor to assign the unique identifier and thirty days for the Reporting entities to incorporate the unique identifier into their data and submit the data. In addition, we ask that a quality control process be built into the vendor's assignment of the unique identifiers as part of the creation of the MPI.

Comment 4: Section .09 Provider Directory Report Submission

As we discussed during our call, please include clarifying language in the regulation to indicate that Pharmacy Benefit Managers who submit stand-alone pharmacy data are not required to submit a Provider Directory Report.

Comment 5: Section .15 Report Submission Methods

This section includes a provision for the Commission to make quarterly updates to the MCDB Submission Manual with three months for the Reporting entities to implement the changes. We respectfully request that the Commission limit changes to the manual to no more frequently than every six months and allow for 180 days for Reporting entities to implement those changes as more frequent changes will be unduly burdensome on the Reporting entities.

Comment 6: Section .16 Request for an Extension of Time

The revised regulation reduces the amount of time from 60 to 30 days that reporting entities can request for an extension to provide data. We respectfully request that the Commission reinstate the 60 day extension option to provide data.

We also note that the Commission will now require that extension requests include the "extraordinary circumstance necessitating the extension request", and while we believe the intent of the Commission is to understand more fully why an extension is being requested, we hope the Commission will not use this new standard to make it harder for payers to receive legitimate extensions of time to provide data.

Comment 7: Section .19 Summaries and Compilations

We note that the draft revised regulation includes existing language and high level direction about the re-release of data to the public.

One critical area that the Commission should consider as more APCD States are implementing price transparency reports and tools concerns the instances in which the

release of data to certain entities identifying specific rates of payment to providers by health plans could lead to anti-competitive activities. While the intent of the Commission's Disclosure of Data to the public is to promote open information to Maryland consumers, this activity could lead to adverse effects on overall market competition that is not in the interest of consumers and will threaten the state's efforts to achieve the health care cost benchmarks it most likely wants to accomplish.

The Commission's APCD Disclosure for Public Use Data Section should include a provision that provides it with discretion to protect against the potential for anti-competitive activities by certain entities that may request APCD data that identifies specific rates of payment by health plan name to providers.

At a federal level, antitrust regulators have recognized the tension between facilitating better information for consumers while limiting the potential for anticompetitive behavior. Under the Sherman Anti-Trust Act, the primary purpose of limited anticompetitive behavior, including collusion to depress prices or artificially inflate prices, is to benefit consumers. As an example, in response to proposed California legislation regarding price transparency, the Department of Justice (DOJ) and Federal Trade Commission (FTC) (the entities that enforce antitrust actions or violations) jointly noted, "Whenever competitors know the actual prices charged by other firms, tacit collusion – and thus higher prices – may be more likely."

The Commission's Disclosure for Public Use language for permitting access to data to consumers should follow and meet the methodological requirements outlined by the DOJ and FTC (see Attached DOJ/FTC Statements of Antitrust Enforcement Policy in Health Care – Statement 6). The DOJ/FTC policy on health care antitrust enforcement states, that without appropriate safeguards or protections, the exchange or release of proprietary or confidential information could facilitate collusion, reduce competition and increase prices and the availability of health care services, all to the detriment of consumers – the patients. Disclosure of a health plan's proprietary or confidential information in its raw form runs counter to the DOJ/FTC policy statement and would not be in the public's interest. Instead it would have the opposite effect, creating potential and serious anti-trust violations and undermine the goals of the Commission's APCD Disclosure for Public Use Data Section.

Given these serious potential issues, we ask that the Commission review data requests for APCD disclosure to the public to determine whether the release or use of data will not result in collusion or anti-competitive conduct, and is not expected to increase the cost of health care for consumers in Maryland by releasing a health plan's identifiable proprietary or confidential information. With that, we propose the following language be included in the Summaries and Compilations Section:

.19 Summaries and Compilations

The Commission shall develop public-use data, summaries, and compilations for public disclosure, pursuant to Health-General Article §§19-103(c)(3), 19-109(a)(6), and 19-134, Annotated Code of Maryland, in compliance with all applicable federal and State laws and regulations. **Any public disclosure or use of data made available to the**

public shall not facilitate collusion or anti-competitive conduct and is not expected to increase the cost of healthcare.

Alternatively, if the Commission would like to implement data disclosure language that has been adopted by another APCD state, we recommend consideration of the following data release language adopted by Rhode Island.

> Data Release Review Board. The Department shall establish a review board for the purposes of reviewing predetermined analytic files to be made available on the Department's website, additional requests for public use data, and requests for public use of restricted release files.
>
> The Board will review predetermined analytic files to be made available on the Department's website, additional requests for public use data, and requests for public use of restricted release files to ensure that members, patients and payer-specific claims payment amounts cannot be identified in any product of the proposed work to be made available.
>
> The Board shall provide a non-binding recommendation to the Director that shall be based upon the application criteria set forth in § #.# of these Regulations.
>
> The Board and Director, as part of their review of whether member, patient and payer-specific claims payment amounts are safeguarded shall also consider if any other data available to the applicant or public that the Board or Director is aware of or reasonably should be aware of could be used to re-identify the member, patient or payer-specific claims payment amounts.
>
> The Director may approve the application for use of restricted release files if he or she is also satisfied that the applicant has demonstrated it is qualified to undertake the study or accomplish the intended use, the applicant requires such files in order to undertake the study or accomplish the intended use; and the applicant has demonstrated appropriate privacy and security controls for access to and storage of restricted release files.

Comment 8: Use of Defined Terms throughout Regulation

We have noted that defined terms, for example Payor and Third Party Administrator, are capitalized in the definition section but not capitalized throughout the MCDB regulation or MCDB Submission Manual. We ask the Commission to format all defined terms throughout the MCDB regulation and MCDB Submission Manual in the same format as is used in Section .02 Definitions of the regulation.

<u>Draft 2013 MCDB Submission Manual Comments</u>

Comment 1: Data Summary Worksheets

UnitedHealthcare and Optum data submitters have developed robust and comprehensive data validation quality checks which are based on the transparency of the state's requirements and the vendor's expectations. These quality checks ensure

that the data is passed to the state and/or their vendor exactly as received from the submitting physician and other providers. UnitedHealthcare and Optum Companies do not critique data elements we receive; instead, we rely on the practitioner to accurately submit the services provided, for the diagnosis, at the appropriate address including spelling of streets, towns, and zip codes.

In addition to this file submission quality check with each file submission, UnitedHealthcare and Optum Companies perform periodic quality checks to ensure that the data is complete and includes all appropriate entities as required by the state. If we find a discrepancy, we report it to a state right away to ensure full compliance with the APCD.

The requirement for all data submitters to complete and submit Data Summary Worksheets is highly complicated and takes more time, rework, effort, and causes a very disproportional burden on us. An example of the extra time and effort associated with the Data Summary Worksheets is the process of submitting the worksheets; some of our data submitters must encrypt, password protect then copy the worksheets onto a CD before mailing the CD to the vendor. The additional burden of creating these reports on a quarterly basis further complicates the submission and extends the timeline needed to prepare and submit the file. We ask that the Commission consider alternative data quality processes in lieu of requiring the submission of Data Summary Worksheets. In each and every one of the other APCD states, there is either a vendor mechanism or a data validation which is systematically built to allow for variance requests and to facilitate the submission of data. In today's Maryland Data Summary Worksheet process, we spend weeks explaining our data, rather than changing the data. The most efficient data quality process we have noted to date is in Colorado, however, Oregon, Utah, Minnesota, Maine, Vermont, New Hampshire, Massachusetts, Kansas could also be contacted to discuss their processes.

Comment 2: New and Modified Specifications - Assignment of Benefits Indicator

Several of our segments do not capture an assignment of benefits indicator as it is not necessary for us to house an assignment of benefits indicator in order to process claims; thus, we will be requesting variances for this field.

Comment 3: New and Modified Specifications – Zip Code + 4

For the Professional, Pharmacy Claims, Institutional and Eligibility files, our Medicare Advantage segment does not consistently receive the zip code plus four; thus, we will be requesting a variance to the 99% threshold. We may also have other submitters with limited data in these fields.

Comment 4: Provider Directory Report

The description of the Provider Directory Report provides for the inclusion of information on all Maryland and out-of-State health care practitioners and suppliers that provided services to applicable enrollees during the reporting period. Please clarify the Commission's expectations regarding the inclusion of information on out-of-State health care practitioners as we have limited information on non-participating providers. Is it

acceptable to run the claims reports, identify the practitioners who provided services to the enrollees and create the Provider Directory Report with available data on those practitioners?

Comment 5: Elimination of Duplication of Reporting

Based on communication with the Commission, we understand that the Commission does not require Reporting entities that perform certain components of the claims adjudication process for the same enrollees to submit duplicate information. We therefore suggest that the following language be added to the Key Submission Requirements section of the Submission Manual:

> Each Reporting entity shall also submit all Medical Claims Data Files, Dental Claims Data Files, Pharmacy Claims Data Files, and associated Provider Files for any claims processed by any sub-contractor on the Reporting entity's behalf.
>
> Reporting entities that are in a contractor/subcontractor arrangement with each other and Reporting entities that perform certain components of the claims adjudication process for the same enrollees under a shared services arrangement shall coordinate with each other to avoid duplicative submissions. Any Reporting entity that administers claims of enrollees as a subcontractor of another Reporting entity or can otherwise demonstrate that its submission of data regarding certain enrollees would result in a duplicative submission may request the Commission to waive its obligation to submit data files for such enrollees.

Comment 6: Race, Ethnicity and Language Data Thresholds

As the Commission considers the implementation of race, ethnicity and language (REL) data thresholds, and as was discussed with the Commission on September 4, 2013, given that we cannot compel our enrollees to provide REL information, UnitedHealthcare commercial products achieve a threshold of between 2% and 3% on the REL fields. The threshold for the Source of Enrollee Race/Ethnicity Information is 95%. We ask the Commission to consider an initial lower threshold of 3% for the specific REL fields.

Comment 7: NPI Field

One of our segments only captures and reports Servicing Practitioner NPIs; the Practitioner NPI used for Billing and the Attending Practitioner Individual NPI are unavailable. We will be requesting a variance for those fields.

Thank you, again, for allowing UnitedHealthcare the opportunity to comment on the draft MCDB Regulation and DSG. Please let me know if you have any questions or concerns regarding these comments.

Sincerely,

Colleen C. Cohan
Associate General Counsel
Legal & Regulatory Affairs
UHC – Mid-Atlantic Health Plan

Attachment

6. STATEMENT OF DEPARTMENT OF JUSTICE AND FEDERAL TRADE COMMISSION ENFORCEMENT POLICY ON PROVIDER PARTICIPATION IN EXCHANGES OF PRICE AND COST INFORMATION

Introduction

Participation by competing providers in surveys of prices for health care services, or surveys of salaries, wages or benefits of personnel, does not necessarily raise antitrust concerns. In fact, such surveys can have significant benefits for health care consumers. Providers can use information derived from price and compensation surveys to price their services more competitively and to offer compensation that attracts highly qualified personnel. Purchasers can use price survey information to make more informed decisions when buying health care services. Without appropriate safeguards, however, information exchanges among competing providers may facilitate collusion or otherwise reduce competition on prices or compensation, resulting in increased prices, or reduced quality and availability of health care services. A collusive restriction on the compensation paid to health care employees, for example, could adversely affect the availability of health care personnel.

This statement sets forth an antitrust safety zone that describes exchanges of price and cost information among providers that will not be challenged by the Agencies under the antitrust laws, absent extraordinary circumstances. It also briefly describes the Agencies' antitrust analysis of information exchanges that fall outside the antitrust safety zone.

A. *Antitrust Safety Zone:* Exchanges Of Price And Cost Information Among Providers That Will Not Be Challenged, Absent Extraordinary Circumstances, By The Agencies

The Agencies will not challenge, absent extraordinary circumstances, provider participation in written surveys of (a) prices for health care services, or (b) wages, salaries, or benefits of health care personnel, if the following conditions are satisfied:

1. the survey is managed by a third-party (e.g., a purchaser, government agency, health care consultant, academic institution, or trade association);
2. the information provided by survey participants is based on data more than 3 months old; and
3. there are at least five providers reporting data upon which each disseminated statistic is based, no individual provider's data represents more than 25 percent on a weighted basis of that statistic, and any information disseminated is sufficiently aggregated such that it would not allow recipients to identify the prices charged or compensation paid by any particular provider.

The conditions that must be met for an information exchange among providers to fall within the antitrust safety zone are intended to ensure that an exchange of price or cost

data is not used by competing providers for discussion or coordination of provider prices or costs. They represent a careful balancing of a provider's individual interest in obtaining information useful in adjusting the prices it charges or the wages it pays in response to changing market conditions against the risk that the exchange of such information may permit competing providers to communicate with each other regarding a mutually acceptable level of prices for health care services or compensation for employees.

B. The Agencies' Analysis of Provider Exchanges Of Information That Fall Outside The Antitrust Safety Zone

Exchanges of price and cost information that fall outside the antitrust safety zone generally will be evaluated to determine whether the information exchange may have an anticompetitive effect that outweighs any procompetitive justification for the exchange. Depending on the circumstances, public, non-provider initiated surveys may not raise competitive concerns. Such surveys could allow purchasers to have useful information that they can use for procompetitive purposes.

Exchanges of future prices for provider services or future compensation of employees are very likely to be considered anticompetitive. If an exchange among competing providers of price or cost information results in an agreement among competitors as to the prices for health care services or the wages to be paid to health care employees, that agreement will be considered unlawful per se.

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 25 MARYLAND HEALTH CARE COMMISSION

Chapter 06 Maryland Medical Care Data Base and Data Collection

Authority: Health-General Article §§19-103(c)(3), (4), (7), and (8), 19-109(a)(1), (6), and (7), 19-133, 19-134, and 19-137, Annotated Code of Maryland

.01 Scope and Purpose.

These regulations establish appropriate methods for collecting and compiling statewide data on selected health care services provided either under a Maryland contract or to Maryland residents by health care practitioners and facilities:

A. From payors;

B. From third party administrators; and

C. Regarding providers for whom the Maryland Health Care Commission otherwise receives data.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Adjudicated" means paid, resolved, or settled.

(2) “Behavioral health services" means mental health services or alcohol and substance abuse services.

(3) "Capitated encounter" means a health care visit in which a health care practitioner or office facility provides a service pursuant to an agreement with a reporting entity for reimbursement on an aggregate fixed sum or per capita basis.

(4) "Commission" means the Maryland Health Care Commission.

(5) "Crosswalk" means a list of all codes and their definitions in a separate file that maps to a specific data field.

(6) "Executive Director" means the Executive Director of the Maryland Health Care Commission.

(7) "Fee-for-service encounter" means a medical care visit in which a health care practitioner or office facility provided a health care service for which a claim was submitted to a reporting entity for payment, and payment was made on a per service basis.

(8) “General health benefit plan” means:

(a) A hospital or medical policy, contract, or certificate issued by a carrier;

(b) A behavioral health services plan;

(c) A pharmacy benefit management services plan;

(d) A vision plan certified by the Maryland Health Benefit Exchange; or

(e) A dental plan certified by the Maryland Health Benefit Exchange.

(9) "Health care service" means a health or medical care procedure or service rendered by a health care practitioner that:

(a) Provides testing, diagnosis, or treatment of human disease or dysfunction; or

(b) Dispenses drugs, medical devices, medical appliances, or medical goods for the treatment of human disease or dysfunction.

(10) “Health Benefit Exchange” or “Exchange” means the Maryland Health Benefit Exchange established as a public corporation under §31-102 of this title and includes the Individual Exchange and the Small Business Health Options Program (SHOP) Exchange.

(11) “Health information exchange” or “HIE” means an entity that creates or maintains an infrastructure that provides organizational and technical capabilities in an interoperable system for the electronic exchange of protected health information among participating organizations not under common ownership, in a manner that ensures the secure exchange of protected health information to provide care to patients. An HIE does not include an entity that is acting solely as a health care clearinghouse, as defined in 45 CFR §160.103. A payor may act as, operate, or own an HIE subject to these regulations.

(12) “HIPAA” means the U.S. Health Insurance Portability and Accountability Act of 1996, P.L.104-191, as implemented and amended in federal regulations, including the HIPAA Privacy and Security rules, 45 CFR §§160 and 164, as may be amended, modified, or renumbered and including as amended by Health Information Technology for Economic and Clinical Health (HITECH) Act.

(13) “Institutional Review Board” has the meaning stated in the federal regulations on the protection of human subjects.

(14) “MCDB Submission Manual” or “Manual” means the composition of data reporting requirements with guidelines of technical specifications, layouts, and definitions necessary for filing the reports required by this chapter.

(15) "Managed care organization" or “MCO” means:

(a) A certified health maintenance organization that is authorized to receive medical assistance prepaid capitation payments; or

(b) A corporation that:

(i) Is a managed care system that is authorized to receive medical assistance prepaid capitation payments;

(ii) Enrolls only program recipients or individuals or families served under the Maryland Children's Health Program; and

(iii) Is subject to the requirements of Health-General Article §15-102.4, Annotated Code of Maryland.

(16) “Master Patient Index” means a database that maintains a unique index identifier for each patient whose protected health information may be accessible through the HIE and is used to cross reference patient identifiers across multiple participating organizations to allow for patient search, patient matching, and consolidation of duplicate records.

(17) "Medical Care Data Base" or “MDCB” means the Maryland Medical Care Data Base.

(18) "Office facility" means a freestanding facility providing:

(a) Ambulatory surgery;

(b) Radiologic or diagnostic imagery; or

(c) Laboratory services.

(19) “Non-Fee-for-Service Medical Expenses Report” means a report with information on lump sum payments made by carriers to providers as part of the carriers’ compensation to the providers for non-claim-based services.

(20) "Payor" means:

(a) An insurer or nonprofit health service plan that holds a certificate of authority and provides health insurance policies or contracts in Maryland;

(b) A health maintenance organization (HMO) that holds a certificate of authority in Maryland; or

(c) For Medical Care Data Base purposes, a third party administrator registered under Title 8, Subtitle 3 of the Insurance Article.

(21) "Pharmacy benefit management services" means:

(a) The procurement of prescription drugs at a negotiated rate for dispensation within the State to beneficiaries;

(b) The administration or management of prescription drug coverage provided by a purchaser for beneficiaries; and

(c) Any of the following services provided with regard to the administration of prescription drug coverage:

(i) Mail service pharmacy;

(ii) Claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to beneficiaries;

(iii) Clinical formulary development and management services;

(iv) Rebate contracting and administration;

(v) Patient compliance, therapeutic intervention, and generic substitution programs; or

(vi) Disease management programs.

(d) “Pharmacy benefit management services” does not include any service provided by a nonprofit health maintenance organization that operates as a group model, provided that the service is provided solely to a member of the nonprofit health maintenance organization and is furnished through the internal pharmacy operations of the nonprofit health maintenance organization.

(22) “Person” means an individual, receiver, trustee, guardian, personal representative, fiduciary, representative of any kind, partnership, firm, association, corporation, or other entity.

(23) "Practitioner" means a person who is licensed, certified, or otherwise authorized under Health Occupations Article, Annotated Code of Maryland, to provide health care services in the ordinary course of business or practice of a profession or in an approved education or training program

(24) "Practitioner federal tax ID number" means the federal tax identification number of the practitioner, practice, supplier or office facility receiving reimbursement for the service provided.

(25) "Practitioner/supplier ID number" means the unique identification number used by the reporting entity to identify the particular practitioner or supplier.

(26) "Primary diagnosis" means the principal diagnosis for the health care service visit.

(27) "Provider” means:

(a) A practitioner;

(b) A facility where health care is provided to patients or recipients, including:

(i) A facility, as defined in Health-General Article §10-101(e), Annotated Code of Maryland;

(ii) A hospital, as defined in Health-General Article §19-301, Annotated Code of Maryland;

(iii) A related institution, as defined in Health-General Article §19-301, Annotated Code of Maryland;

(iv) A health maintenance organization, as defined in Health-General Article §19-701(g), Annotated Code of Maryland;

(v) An outpatient clinic; and

(vi) A medical laboratory; or

(c) The agents and employees of a facility who are licensed or otherwise authorized to provide health care, the officers and directors of a facility, and the agents and employees of a health care provider who are licensed or otherwise authorized to provide health care.

(28) “Reporting entity” means a payor or a third party administrator that is designated by the Commission to provide reports consistent with this chapter to be collected and compiled into the Medical Care Data Base.

(29) “State-designated health information exchange” or “State-designated HIE” means an HIE designated by the Maryland Health Care Commission and the Health Services Cost Review Commission pursuant to the statutory authority set forth in Health-General Article §19-143, Annotated Code of Maryland.

(30) "Supplier" means a person or entity, including a health care practitioner, which supplies medical goods or services.

(31) "Third party administrator" means a person that is registered as an administrator under Title 8, Subtitle 3 of the Insurance Article.

(32) “Qualified dental plan” means a dental plan certified by the Maryland Health Benefit Exchange that provides limited scope dental benefits, as described in § 1311(c) of the Affordable Care Act and Insurance Article §31-115, Annotated Code of Maryland.

(33) “Qualified health plan” means a general health benefit plan that has been certified by the Maryland Health Benefit Exchange to meet the criteria for certification described in §1311(c) of the Affordable Care Act and Insurance Article §31-115, Annotated Code of Maryland.

(34) “Qualified vision plan” means a vision plan certified by the Maryland Health Benefit Exchange that provides limited scope vision benefits, as described in the Insurance Article §31-108(b)(3) Annotated Code of Maryland.

.03 Persons Designated to Provide Data to the Commission.

A. Payors. By December 31 of each year, the Commission shall make available a list of each payor meeting the criteria for designation as a reporting entity and who shall file the reports under this chapter in the following year.

(1) The Commission shall designate as a reporting entity each payor whose total lives covered exceeds 1,000, as reported to the Maryland Insurance Administration.

(2) The Commission shall designate as a reporting entity each payor offering a qualified health plan, qualified dental plan, or qualified vision plan certified by the Maryland Health Benefit Exchange, Insurance Article §31-115, Annotated Code of Maryland.

(3) The Commission shall designate as a reporting entity each payor that is a managed care organization participating in the Maryland Medical Assistance Program in connection with the

enrollment of an individual in the Maryland Medical Assistance Program or the Maryland Children's Health Program.

(4) The Commission may conduct surveys as needed to fulfill the purposes of the MCBD.

(a) The Commission may conduct a survey of any payor to determine if the payor is required to report data or for other purposes consistent with this chapter.

(b) If necessary, the Commission may institute an annual survey to obtain information needed to determine and designate third party administrators whose annual covered lives report filed with the Maryland Insurance Administration does not delineate the number of covered lives for the following:

(1) A behavioral health services plan; or

(2) A pharmacy benefit management services plan.

(c) A payor shall timely report information sought by the Commission in a survey.

B. Data Otherwise Collected by the Commission from Payors or Providers.

(1) A payor's reports are considered submitted to the Commission if they are contained within the submission of another payor.

(2) For the purpose of supplementing the MCDB, the Commission may include information that the Commission has otherwise received regarding providers and services.

C. Data Collected from other State or Federal Agencies. The Commission designates and selects any data obtained from a state or federal agency to be a part of the MCDB for use consistent with this chapter.

.04 Process for Submitting Data.

A. The Commission shall provide each reporting entity with an annual update to the MCDB Data Submission Manual, and each current submission update available as specified in Regulation .15 of this chapter.

B. Each reporting entity shall provide each of the following reports, if applicable:

(1) Professional Services Data Report;

(2) Pharmacy Data Report;

(3) Provider Directory Report;

(4) Institutional Services Data Report;

(5) Eligibility Data Report;

(6) Plan Benefit Design Report;

(7) Dental Data Report; and

(8) Non-Fee-for-Service Medical Expenses Report.

C. An MCO shall provide each required report to the Commission through the Maryland Medical Assistance Program, which will provide the MCO reports and related information to the Commission.

.05 Time Period for Submitting Data Reports.

A. For services rendered in calendar year 2013:

(1) Only those reporting entities designated under Regulation .03A(1) shall submit to the Commission a complete set of the entity's data for that period in the form and format described in Regulations .07 - .14 of this chapter by June 30, 2014.

(2) The submission shall consist of all claims for services provided in 2013 that are adjudicated between January 1, 2013 and April 30, 2014, four months after the end of the reporting period.

B. For services rendered in calendar year 2014 and thereafter, each reporting entity shall submit to the Commission a complete set of the entity's data for claims paid during each quarter in the form and manner described in Regulations .07 – .14 of this chapter within 2 months of the last day in the applicable quarter, unless a less frequent submission is specified by the Commission, with notice to reporting entities that includes a dated posting on the Commission's website.

.06 Protection of Confidential Information Generally and in Submissions.

A. Filing Data Using Encryption.

(1) To assure that confidential records or information are protected, each reporting entity shall encrypt each of the following data elements in such a manner that each unique value for a data element produces an identical unique encrypted data element:

(a) Patient or enrollee identifier; and

(b) Internal subscriber contract number.

(2) In order to maintain a consistent and unique identifier for each patient across providers, payors, and services, the Commission shall:

(a) As necessary, provide each reporting entity with an encryption algorithm using one-way hashing consistent with the Advanced Encryption Standard (AES) recognized by the National Institute of Standards and Technology; and

(b) Beginning with 2014 submissions, direct each reporting entity to :

(i) Provide selected data to the State-designated HIE for the creation and encryption of a Master Patient Index; and

(ii) Include Master Patient Index identifiers received from the State-designated HIE in its eligibility data report, as provided in Regulation .11.

(3) Each reporting entity shall maintain the security and preserve the confidentiality of the encryption algorithms provided by the Commission.

B. Security Safeguards.

(1) Any person accessing or retrieving data collected for and stored in the Medical Care Data Base shall use safeguards developed in accordance with State agency data systems security practices.

(2) Only an authorized individual designated in writing by the Executive Director, or his designee, shall have access to the Maryland Medical Care Data Base.

(a) The Executive Director, or his designee, shall establish a scope of access for each authorized individual.

(b) Each authorized individual shall sign a confidentiality security agreement as specified by the Commission.

C. Disclosure of Data for Research Use.

To ensure that confidential or privileged patient information is kept confidential, prior to any disclosure of data that contains “directly or indirectly identifiable health information", as defined in HIPAA:

(1) A review shall be conducted by an appropriate Institutional Review Board, as provided in COMAR 10.25.11;

(2) The Maryland Medical Assistance Program (Medicaid) shall review and approve any request for the release of Medicaid data.

.07 Professional Services Data Report Submission.

A. Each reporting entity shall submit a professional services data report that provides the data for each fee-for-service and capitated encounter provided by a health care practitioner or office facility.

(1) This report shall include all health care services provided:

(a) To each Maryland resident insured by that entity under a fully insured or a self-insured contract; and

(b) To each non-Maryland resident insured under a Maryland contract.

(2) The health care services in this report shall include but are not limited to behavioral health services and vision services.

B. Each professional services data report shall contain the information specified by the Commission in its annual update to the MCDB Data Submission Manual and be filed in a form and manner specified in the Manual.

.08 Pharmacy Data Report Submission.

A. Each reporting entity shall submit a pharmacy data report for each prescription drug encounter for services provided by a pharmacy located in or out of the State. This report shall include all pharmacy services provided to each Maryland resident insured under a fully insured contract or a self-insured contract, and to each non-Maryland resident insured under a Maryland contract.

B. Each pharmacy data report shall contain the information specified by the Commission in its annual update to the MCDB Data Submission Manual and be filed in a form and manner specified in the Manual.

.09 Provider Directory Report Submission.

A. Each reporting entity shall submit a provider directory report detailing each health care practitioner or supplier that provided services to any enrollee of that reporting entity during the reporting period. This report shall contain information for each in-State Maryland practitioner or supplier, and for each out-of-State practitioner or supplier, that has served a Maryland resident or a non-Maryland resident under a Maryland contract.

B. Each provider directory report shall include a crosswalk to each practitioner or supplier ID listed in the professional services data report submitted under .07 of this regulation or the pharmacy data report submitted under .08 of this regulation.

C. Each provider directory report shall contain the information specified by the Commission in its annual update to the MCDB Data Submission Manual and be filed in a form and manner specified in the Manual.

.10 Institutional Services Data Report Submission.

A. Each reporting entity shall submit an institutional services data report that reports all institutional health care services provided to each Maryland resident insured under a fully insured contract or self-insured contract, and each non-Maryland resident insured under a Maryland contract, whether those services were provided:

(1) By a health care facility located in-State or out-of-State; or

(2) Under a general health benefit plan.

B. Each institutional services data report shall contain the information specified by the Commission in its annual update to the MCDB Data Submission Manual and be filed in a form and manner specified in the Manual.

.11 Eligibility Data Report Submission.

A. Each reporting entity shall submit an eligibility data report that provides information on the characteristics of each enrollee that is a Maryland resident insured under a fully insured contract or a self-insured contract, and that is a non-Maryland resident insured under a Maryland contract for services covered under each policy or contract issued by the reporting entity that are subject to this chapter.

B. Each eligibility data report shall contain the information specified by the Commission in its annual update to the MCDB Data Submission Manual and be filed in a form and manner specified in the Manual.

.12 Plan Benefit Design Report.

Each plan benefit design report shall contain the information specified by the Commission in its annual update to the MCDB Data Submission Manual and be filed in a form and manner specified in the Manual.

.13 Dental Data Report.

Each dental data report shall contain the information specified by the Commission in its annual update to the MCDB Data Submission Manual and be filed in a form and manner specified in the Manual.

.14 Non-Fee-for-Service Medical Expenses Report.

Each Non-Fee-for-Service Medical Expenses Report shall contain the information specified by the Commission in its annual update to the MCDB Data Submission Manual and be filed in a form and manner specified in the Manual.

.15 Report Submission Methods.

A. When a reporting entity collects more granular information than required by this chapter, it shall provide a conversion table that describes how internal values are mapped to each required category.

B. The MCDB Data Submission Manual shall contain technical specifications, encryption algorithms, layouts, required reports, and definitions for each reporting entity.

(1) The Commission shall provide an annual MCDB Submission Manual by November 21 of each year to be used for the reporting periods in the subsequent year.

(2) The Commission may correct incomplete or erroneous information in the MCDB Submission Manual,as necessary and provide notice of each correction on the Commission website and by email to the contact persons designated by payors.

(3) The Commission shall timely post the annual MCDB Data Submission Manual on the Commission website and provide notice in the Maryland Register.

C. The Commission may require that each reporting entity electronically submit sufficient demographic information on each enrollee to create a Master Patient Index.

(1) The Commission may require that the reporting entity provide this information to the State-designated health information exchange solely for this purpose.

(2) The information shall be submitted in a manner consistent with all relevant federal and State privacy laws and regulations.

.16 Request for an Extension of Time.

A. A reporting entity may request an extension of an additional 30 days time to provide the required data report.

B. For a 30 day extension request to be considered by Commission staff, the reporting entity shall submit a written request to the Executive Director at least 30 days before the quarterly submission date that includes:

(1) The extraordinary cause necessitating the extension request; and

(2) A proposed date, which is no more than 30 days after the initial quarterly submission date, when the reporting entity will provide the quarterly data to the Commission.

.17 Request for an Annual Waiver or Format Modification.

A. Annual Waiver Request. When a reporting entity is not able to submit a data report as set forth in this chapter, it shall file with the Commission by March 15 of the year for which a waiver is sought a written request for an annual waiver that shall include:

(1) An explanation of why the reporting entity is not able to provide the data report, including any extraordinary circumstances; and

(2) Any supporting documentation required.

(a) A general health benefit plan shall include an affidavit from an officer of the organization stating that its total lives covered does not exceed 1,000, as reported to the Maryland Insurance Administration.

(b) A qualified health benefit plan, a qualified vision plan or a qualified dental plan shall include a relevant document from the Health Benefit Exchange indicating that the entity's filing of the data is not required.

(c) A third party administrator shall include an affidavit from an officer of the organization stating that its total lives covered does not exceed 1,000, as reported to the Maryland Insurance Administration.

B. Format Modification Request. When a reporting entity is not able to provide all the information required in .07 - .14 of this Regulation, it shall file with the Commission a written request for a format modification 30 days before the applicable submission date that shall include:

(1) The extraordinary circumstances surrounding the reporting entity's inability to submit values for a specific data element;

(2) An explanation of each reason why a format modification is necessary; and

(3) A detailed description of the reporting entity's proposed layout or submission method, or both when applicable.

C. The Executive Director shall provide the reporting entity with a written decision within 30 days of the filing of a completed request.

D. Appeal of the Executive Director's Decision. The aggrieved party may file a written request for Commission review of the Executive Director's written decision within14 days of the decision.

(1) The Commission may provide an opportunity for the reporting entity to present argument to the Commission.

(2) The Commission may affirm, reverse, or modify the decision of the Executive Director.

(3) The decision by the Commission shall be by a majority of the quorum present and voting.

.18 Failure to File Data Reports.

A reporting entity that does not timely file a data report may be subject to penalties provided in COMAR 10.25.12.

.19 Summaries and Compilations.

The Commission shall develop public-use data, summaries, and compilations for public disclosure, pursuant to Health-General Article §§19-103(c)(3), 19-109(a)(6), and 19-134, Annotated Code of Maryland, in compliance with all applicable federal and State laws and regulations.

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Regulations .01—.14 repealed and new Regulations .01—.14 adopted effective August 21, 2000 (27:16 Md. R. 1525)

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Regulations .01—.14 repealed and new Regulations .01—.17 adopted effective April 19, 2010 (37:8 Md. R. 617)