



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; ~~strike through~~ 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 42 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 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.~~ 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 conduct 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.