DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR DRUG AND HEALTH PLAN CHOICE

TO: All Medicare Advantage Organizations and Part D Sponsors

FROM: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

RE: Medicare Part C and Part D Reporting Requirements and Data Validation

DATE: November 23, 2009

We would like to express our thanks to Medicare Advantage Organizations (MAOs) and Part D sponsors for the comments on the draft materials related to the Part C and Part D reporting requirements data validation initiative. These comments were very helpful in our efforts to identify areas requiring clarification and further revision.

As a result of the comments received from MAOs, Part D sponsors, and industry representatives, we are clarifying the timeframe for the implementation of the Part C and D data validation initiative. Specifically, we clarify that the data validation for Part C and D reporting requirements will be initiated in 2011 for CY 2010 data. Thus, we intend that the first data validation audits for Part C and D reporting requirements data to occur during the period of approximately March 2011 through May 2011.

We continue to believe that only an independent data validation audit conducted by an external entity under contract to the MAO or PDP sponsoring organization would ensure that reported data used to develop plan performance measures are credible to other stakeholders, and that information used to respond to Congressional and public inquiries are reliable. However, we also believe, based in part on comments received, that we should focus the data validation efforts on the most critical data for monitoring and reporting purposes, and rely on periodic program audits and other targeted inquiries to ascertain the validity of other reporting data. In addition to focusing on data validation activities, we have also carefully reviewed the underlying reporting requirements for Part C and D as a whole and have determined that we will be suspending collection of some data for 2010. Our focus in the coming weeks will be on identifying those data that we will no longer require for reporting purposes and on determining the specific data elements that require validation.

More information will be made available to you on the specifics of these implementation changes in the near future. Information on data that will be suspended will be included as part of updated information in our "Part C Reporting Requirements Technical Specifications" and "Part D Reporting Requirements Technical Specifications," which will be released via HPMS in the next few weeks and then posted on our website at (http://www.cms.hhs.gov/). Information on the revised data validation standards will be posted as part of an upcoming Paperwork Reduction Act package, which will provide further opportunity for MAOs and Part D sponsors to provide comment.

Thank you for your interest in this important matter. Attached to this memorandum is a "Question and Answers" (Q and A) document that addresses many of the questions we received during our recent comment period. Additional questions on Part C reporting should be e-mailed to Partcplanreporting@cms.hhs.gov. Questions on Part D reporting should be e-mailed to: PartD-PlanReporting@cms.hhs.gov.

Q & As
Parts C & D Data Validation
Standards and Procedures

Background

One provision of our recently proposed rule, *Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs* (CMS-4085-P; RIN 0938-AP77), is to require MAOs and Part D sponsors to undertake an independent data validation audit in accordance with CMS specifications on reported Part C and Part D data that would be effective in CY2011. We believe that only an independent data validation audit conducted by an external entity under contract to the MAO or PDP sponsoring organization would ensure that the results of the audit are in accordance with CMS specifications, that data used to develop plan performance measures are credible to other stakeholders, and that information used to respond to Congressional and public inquiries are reliable.

We are working with a contractor to revise the data validation specifications that will be utilized to ensure that the goals of reliability, validity, completeness, and comparability are met at the conclusion of the data validation audit. These specifications will focus on how organizations and sponsors compile numerators and denominators, take into account appropriate data exclusions, and verify calculations, computer code, and algorithms. In addition, they will be used to inform how the MAOs, cost plans, and Part D sponsors collect, store, and report data. We expect that these specifications will be utilized by the auditors hired by MAOs and Part D sponsors to conduct the data validation audits, the results of which will be forwarded to us. We expect to make these revised specifications available on our website for public comment early next year.

Q & As

Q1: What is the main purpose of the independent data validation?

A1: The purpose of the independent data validation is to ensure that health plans are reporting health and drug plan data that are reliable, valid, complete, comparable, and timely. Audited data will ensure that health and drug plans are on equal footing for public reporting and will provide CMS with assurance that data are consistently collected by plans

Q2: Why are we requiring an independent data validation?

A2: We believe that only an independent data validation conducted by an external entity will ensure that the data used to develop plan performance measures are credible to other stakeholders, and that information used to respond to Congressional and public inquiries are reliable for monitoring plans.

Q3: How does this independent data validation differ from other audits of health plans?

A3: This will not be a program audit; instead it will be an independent validation of data measures, elements, and the systems and processes underlying the collection, compiling, and reporting of those data and elements. We will ensure that the data validation audit is not duplicative of program audits.

Q4: Who will be responsible for acquiring the independent data validation resources?

A4: Sponsors will be responsible for acquiring the resources through a contractor or through other means.

Q5: Can sponsors use their own staff to perform the data validation?

A5: In 2011, we are requiring that the data validation be conducted by an independent entity. Therefore, sponsors may not use their own staff to conduct the data validation although they may use their own staff to assist the auditors in obtaining the information, data, and documents needed to complete the audit.

Q6: What will be the focus of the data validation standards and procedures?

A6: The main focus will be on how the sponsor collects, stores, and reports data. Standards and procedures will also focus on how sponsors compile numerators and denominators, take into account appropriate data exclusions, and verify calculations, computer code and algorithms.

Q7: When will the first independent data validation begin?

A7: The first independent data validation will begin in calendar year 2011, probably between March and May.

Q8: How often will the independent data validations take place?

A8: The independent data validations will occur once per year.

Q9: Will all Part C and D be independently validated each year?

A9: CMS will clarify the Part C and D data and specific elements of those data that will be validated.

Q10: At what level of the organization will the data be validated?

A10: The data will be validated at the contract level unless they are collected at a lower level. In that case, they will be validated at the plan benefit package level.

Q11: Who will develop the data validation standards and procedures?

A11: CMS has worked with a contractor to develop the draft standards and procedures. These data validation standards and procedures will be released as part of Paperwork Reduction Act package for public comment in early 2010, and we expect them to be finalized by late summer.

Q12: Will CMS develop standards or criteria for hiring an auditor?

A12: The standards and criteria for hiring an auditor have been developed in draft for comment. We are still evaluating the comments and determining whether additional guidance is needed from CMS.

Q13: Will the independent data validation standards and procedures be tested before they are implemented?

A13: Yes, the standards and procedures will be tested at two pilot sites.

Q14: Will plans receive a manual of data validation standards and procedures prior to the conduct of the data validation?

A14: Yes, plans will receive a manual of the standards and procedures prior to their data validation. We anticipate that CMS will offer training opportunities related to these standards and procedures.

Q15: Will the sponsor be "graded" on the results of the independent data validation?

A15: Yes, a scoring system will be developed and a "pass" or "not pass" will be assigned based on information reported to us by the independent data validation contractor hired by the MAO or Part D sponsor.

Q16: What is the purpose of the "Organizational Assessment Instrument" (OAI)?

A16: The purpose of the OAI is to gain information on the sponsoring organization at the start of the formal data validation process. This assessment instrument will be used by data validation auditors to help them to understand the systems and processes they need to review as part of their data validation. It will be used to record information about the organization's data collection and reporting systems and the specific data collection and reporting processes for the Part C and Part D data.

Q17: When will the OAI be administered?

A17: The OAI will be administered at the start of each yearly audit and will be used to assess improvement in data collection and reporting systems over time.

Q18: What will be contained in the OAI?

A18: The OAI will contain sections on various important aspects of the organization including medical services, enrollment, medical record review, credentialing, the member call center, and data processing. It should provide auditors with information about the sources of Part C and Part D data, how the data are organized in data bases, how the data are retrieved, how the data are compiled, and how the data are (or will be) used to administer the organization's programs and services and monitor the organization's performance. The OAI will be applicable to all phases of the project.

Q19: How will the data validation results be reported to CMS?

A19: Although this has not been finalized, the data validation contractors will likely report results through the Health Plan Management System (HPMS). More information will be forthcoming at a later date.

Q20: What are the consequences of failure to meet the technical specifications of the data validation or to be found deficient in any substantive area of the data validation?

A20: Sponsors that do not meet all the technical specifications could be subject to compliance actions. Sponsors that are found to be deficient will be requested to develop corrective action plans or could be subject to other enforcement actions. A "not pass" on an independent data validation will be treated the same as failure to submit required data, which in turn will be considered non-compliant. Additionally, CMS' performance measurements may be adjusted to reflect an organizations' non-compliance with our requirements.

Q21: Is there an enrollment threshold for the data validation not to be conducted?

A21: There is no enrollment threshold, although obviously plans with zero enrollment will not be subject to the data validation.

Q22: Will plans have the right to appeal the findings of the data validation audit?

A22: No, the plan will not have the right of appeal. The plan contracts with an independent entity. The plan either agrees with the findings of the independent entity or disagrees. This process solely involves the plan and the independent entity, resulting in the final findings.

Q23: Will non-renewing plans be subject to the data validation audit?

A23: Non-renewing plans must report the data per the reporting requirement technical specifications, but these plans do not need to validate the data.

Q24: Please clarify which set of reporting requirements for Part C and Part D will undergo the data validation review in 2010 and 2011.

A24: Data validation reviews will not occur in 2010 as originally stated. Per the CMS proposed rule, *Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs* (CMS-4085-P; RIN 0938-AP77), data validation reviews will begin in 2011 and assess data submitted per the 2010 reporting requirements for Part C and Part D organizations.

Q25: Will there be multiple data validation reviews throughout the year, depending on the submission date for the reporting requirements, or will there be one data validation review that incorporates all reporting requirement submissions?

A25: Sponsoring organizations will undergo a retrospective[1] data validation review once per year beginning in 2011. This annual review will incorporate all submissions based on the previous calendar year's reporting requirements (e.g., 2010 reporting requirements).

Q26: The Part C Benefit Utilization data elements have a report submission date of 8/31/11. How will the data validation reviews that take place in the spring of 2011 incorporate reporting of these elements?

A26: As data validation reviews will occur annually in the spring, the data validation review for Part C Benefit Utilization will be performed prospectively. CMS is developing the process for conducting this prospective data validation.

[1] All data validation reviews, with the exception of Part C Benefit Utilization, will be retrospective. See Q9/A9 for more detail.