BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

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March 13, 2009

Ms. Charlene Frizzera
Acting Administrator
The Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Prescription Drug Programs; Revisions to Medicare Part D Reporting Requirements for CY 2010 (Form Number CMS-10185; OMB# 0938-0992)

Dear Ms. Frizzera:

The Blue Cross and Blue Shield Association (BCBSA) appreciates the opportunity to comment on CMS's information collection relating to the Revisions to the Medicare Part D Reporting Requirements for CY 2010 (Form Number CMS-10185; OMB# 0938-0992) as published in the *Federal Register* on January 14, 2009 (74 *Fed. Reg.* 2078).

BCBSA represents the 39 independent Blue Cross and Blue Shield Plans (Plans) that currently provide health care coverage to more than 102 million Americans. The majority of our Plans contract with CMS to provide Medicare Part D Plans in the market today. We are pleased to serve several million Medicare beneficiaries under these important programs.

Plans appreciate CMS continued efforts to review and adjust Plans' reporting obligations under the Part D Program, including the changes reflected in the Draft CY 2010 Medicare Part D Reporting Requirements (Draft Reporting Requirements), in order to collect the data CMS requires to administer the Part D Program in a manner that is as least burdensome to Plans as possible. BCBSA is concerned, however, that several of the proposed changes seek information that is not feasible for Plans to identify, collect and report. For example, several of the new data elements required in connection with Plans' Medication Therapy Management (MTM) Programs seek information that can only be confirmed through medical record review, and stand-alone prescription drug plans generally do not have access to this information. We recommend that CMS eliminate these data elements or, in the alternative, modify the requisite data element to be based on information Plans have ready access to and are not unreasonable from a cost perspective to collect. .

BCBSA considers compliance and detection of fraud, waste and abuse as a top priority. However, BCBSA strongly objects to CMS new efforts to require Plans to self-report information on potential fraud, waste and abuse through the Draft Reporting Requirements. We support Plan' maintenance of compliance programs and believe it is in Plans, as well as Medicare beneficiaries, interest to maintain intense efforts to combat fraud, waste and abuse. We oppose mandatory self-reporting of violations,

however, and have raised our concerns to CMS on numerous occasions.[1] In fact, CMS has proposed – and subsequently withdrawn or not acted upon – mandatory self-reporting regulatory requirements on several occasions. This is appropriate in light of the fact that self-reporting is not required under any provision established in law, and BCBSA and Plans object to CMS efforts to adopt mandatory self-reporting through the Draft Reporting Requirements.

Mandatory self-reporting is not required for providers in traditional Medicare and also places unreasonable business risks on Plans that are partnering with CMS in the Medicare Advantage and Part D Programs. CMS should withdraw these reporting requirements.

Attached to this letter is a chart describing our comments and concerns as well as recommendations for modifications to the Reporting Requirements. These comments and suggestions are offered in a spirit of partnership with CMS and our shared goal of improving the Part D Program's operations for both CMS and Plans.

Questions on our comments may be directed to Jane Galvin, Director, Regulatory Affairs at BCBSA, at 202.626.8651 or by e-mail at Jane.Galvin@bcbsa.com.

We look forward to continuing to our continuing partnerships with CMS in the Medicare Part D Program.

Sincerely,

Jane Galvin

Jane Galvin
Director, Regulatory Affairs, Office of Representation and Policy

Attachment

[1] *See, e.g.*, BCBSA Letter to Herb Kuhn, Acting Deputy Director, CMS, on Proposed Rule CMS-4124-P: Medicare Program: Revisions to the Medicare advantage and Part D Prescription Drug Contract Determinations, Appeals and Intermediate Sanctions Processes (July 24, 2007) (attached).

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Blue Cross and Blue Shield Association
Comments on the Medicare Program; Medicare Prescription Drug Program
Revisions to Medicare Part D Reporting Requirements for CY 2010
(Form Number CMS-10185; OMB# 0938-0992)
January 14, 2009

Reporting Section	Comments and Concerns	BCBSA Recommendations
Enrollment	BCBSA supports CMS collection of enrollment data with the level of specificity set out in the Draft CY 2010 Reporting Requirements (Draft Reporting Requirements). Q4 data, however, will reflect all enrollment changes that occur during the annual enrollment period, and MA and MA-PD Plans also will have significant data processing in Q1 relating to the open enrollment period. Given Plans' other responsibilities relating to Member enrollment and the overlap in personnel handling these various resources, these additional reporting requirements would hinder Plans' ability to ensure data that is submitted to CMS is accurate and complete.	BCBSA recommends that CMS adopt semi-annual reporting periods, rather than the existing quarterly periods, as this would provide Plans with additional time to collect, analyze and validate data prior to its submission without undermining CMS's access to detailed information. In the alternative, if CMS maintains the quarterly reporting periods, BCBSA and Plans recommend that CMS extend by one or two months the deadline by which such data is due to the agency.

Reporting Section	Comments and Concerns	BCBSA Recommendations
MTM Programs	Section V.I.K: CMS requests data on item the "average amount of time spent to complete an annual comprehensive medication review per MTMP enrollee (hh:mm)." Tracking this data must be done manually, making it a labor intensive and costly effort. Additionally, it seems this data would be more valuable to Plans than to CMS because the measurement of time offers little indication of the quality of the medication review and is not a data element that provides an accurate comparison of Plan activity. Section V.II.N: CMS request for data on the "number provider interventions," is too vague to provide reliable information of Plan MTM programs or to enable Plan comparisons, and thus is a laborious, resource-intensive activity with few tangible benefits. Whether this reporting element includes general provider interventions, such as educational mailings on specific topics, or if it only includes provider interventions that are member/patient specific. Additionally, tracking this data would be labor intensive and burdensome to plans' resources. Sections V II.O - T: Plans believe that the data required in elements O through T can only be confirmed by medical record review, making these reporting requirements unreasonable for Plans, particularly stand alone prescription drug plans that lack access to Members medical record.	Section V.II.K: CMS should eliminate collection of this data element Section V.II.N.: CMS should eliminate collection of this data element. In the alternative, CMS shall provide more specific guidance as to what constitutes a "provider intervention" for purposes of this data collection. Does it include provider interventions to a specific member or general provider interventions, such as mailings on a specific topic? Sections V II.O - T: CMS should modify these data elements so that only the information Plans can collect and confirm, based on its own operations, is submitted to CMS twice a year and not quarterly.
Grievances	Although Plans generally support CMS's collection	BCBSA recommends that CMS eliminate the "#

Reporting Section	Comments and Concerns	BCBSA Recommendations
	of data relating to grievances, in light of its importance in administering the Part D Program, CMS data elements in Section IX are redundant and vague. CMS requests data or grievances filed by LIS and non-LIS beneficiaries in two separate categories that lack meaningful distinction. Furthermore, categorization of grievances is arbitrary and lacks any analytical or other basis for Plan evaluation or comparison.	of Distinct Beneficiaries Filing a Grievance" reporting requirements because it is redundant to other data collection in Section IX. CMS also should eliminate the requirement that Plans classify their grievances, or, as the alternative, provide greater specificity as to the categories of grievances to make the data collection and analysis more meaningful.
Fraud, Waste and Abuse and Compliance Programs	BCBSA and Plans have significant concerns regarding Section XVIII of the Draft Reporting Requirements, which essentially require Plans to self-report incidents of fraud and abuse, as defined by CMS through vague definitions and categories. BCBSA has commented on CMS's previous self-reporting proposals (*see, e.g.*, the attached July 2007 letter to Herb Kuhn that includes BCBSA's opposition to the self-reporting regulatory requirement proposed in May 2007), stating, among other points, that CMS lacks the authority to adopt a self-reporting requirement for the Medicare Advantage and Part D Programs. CMS cannot, and should not, adopt such a requirement through reporting requirements that are not subject to the rulemaking procedures set out in the Administrative Procedures Act. In addition to concerns about the self-reporting proposal in its entirety, BCBSA believes the provisions in the Draft Reporting Requirements are inappropriately vague, will force Plans to launch resource-intensive investigations to	BCBSA and Plans strongly urge CMS to eliminate this section of the Draft Reporting Requirements as the agency lacks the authority to mandate self-reporting and the requirements themselves are unworkable. We believe that the current systems in place are working and new requirements in this areas are not necessary.

Reporting Section	Comments and Concerns	BCBSA Recommendations
	respond to allegations and complaints that do rise to the level of concern, and otherwise impose on Plans administrative burdens and potential legal liability that are inappropriate Definitions of Fraud Incident and Abuse Incident: These definitions are inappropriately vague and require Plans to make judgments about an incident, including whether an action is intentional or negligent or merely a mistake as well as whether something constitutes deception or a misrepresentation or is false. In order to make such judgments, the Plan would be obligated to conduct an investigation, which may or may not be an appropriate action given the alleged incident or complaint. Moreover, Plans could be increasing their potential liability for an alleged incident or complaint based on this classification requirement, which is an unreasonable business risk for CMS to impose on Plans partnering with CMS to administer the Part D Program. Data Elements: BCBSA objects to the data elements that CMS incorporates into Section XVIII, as the descriptions are imprecise and vague. What constitutes "inappropriate billing" versus "providing false information" is unclear, as is the type of incident that constitutes "potential" fraud or abuse. Furthermore, making these determinations and classifications would require Plans to judge activities, and such judgments would not be possible without conducting an investigation of	

Reporting Section	Comments and Concerns	BCBSA Recommendations
	each and every incident. Such investigations, however, may not be warranted by the circumstances but, because of these reporting requirements, would be necessary to meet these administrative obligations. In addition to creating extensive and costly administrative burdens, these reporting requirements potentially expand Plans liability; depending on how the Plan categorizes an incident and what, if any, action is taken in response to such categorization. This is a business risk that CMS should not impose on its Plan partners as it likely will have the effect of reducing Plan participation in the Programs. Finally, arbitrary nature of the judgments and other components that are inherent in collecting and reporting data to CMS eliminate any data consistency and prevent meaningful comparisons within a Plan's own data and among various Plans. Thus, CMS and Plans gain little benefit from these reporting requirements, but the significant administrative costs and liabilities Plans would assume undermine their continued participation in the Program.	