

Comments on Draft 2012 Part D Reporting Requirements

Section number and Page number	Issue
Section I Enrollment & Disenrollment	
Paragraphs 4 & 5 Page 5	These paragraphs mention transactions that will be going away with the April 2011 software release.
1.B Page 5	It's unclear whether "complete" means complete when received or complete following a request for information. In other words, are 1B and 1C exclusive of each other, or could some of the enrollments in 1C also be in 1B?
1.J Page 6	It's unclear exactly what is meant by "employed" agents and brokers.
2.A Page 6	Should plans include only voluntary disenrollments for this element? Meaning we would exclude out-of-area or incarcerated disenrollments.
2.B Page 6	It's unclear whether "complete" means complete when received or complete following a request for information.
2.C Page 6	Should the the number of disenrollment requests denied include both denials for ineligibility and denials for not responding to a request for information?
2.D Page 6	Disenrollments due to failure to pay premium would not be voluntary and based on the answer to 2.A above would probably not be included in "total reported in A."

Comments
Please remove the applicable transactions that will be going away with the April 2011 software release (e.g. 60,62,)
Please clarify.
Please provide a definition for employed agents/brokers.
Please add clarifying language.
Please clarify.
Please add clarifying language.
Please clarify.

Medco Health Solutions, Inc.
Comments on CY 2012 Draft Reporting Requirements

Medco Health Solutions, Inc. respectfully submits the following comments on the CY 2012 Draft Reporting Requirements:

Section I. Enrollment and Disenrollment

- Effective 4/18/2011 CMS is introducing changes to the enrollment processing rules (MARx System Re-design – April Software release). The change result in elimination of certain type codes such as code 60, 62. Therefore section below should be modified accordingly to include proper codes:
Data elements 1.A-1.P must include all enrollments (60, 61, 62 and 71 transactions)

Section VI- Pharmacy support Electronic prescribing

Recommend that CMS eliminate the need for plan sponsors to report this information. It would be more efficient if CMS received this information from a central source such as NCPDP since pharmacies that support electronic prescribing would do so for all Plan Sponsors for which the pharmacy is a network participant. This capability is not a Plan Sponsor specific capability.

Section IX. Coverage Determinations and Exceptions

It is recommended for Report element A- The total number of pharmacy transactions in the reporting time period be further refined to specify the types of pharmacy transactions should be included (example specifying only paid claims, rejected claims and reversed claims and eliminating any other types of transactions such as adjustments which are purely done for financial reasons and do not impact drug utilization management).

Can CMS please clarify the rationale for reporting multiple transactions for the same beneficiary, same drug, same pharmacy, same rejection reason on the same date of service?

Section IX. Coverage Determinations and Exceptions

- 1) All the following elements use the word “processed” in the reporting period. Can CMS clarify what they mean by “processed?” Is it CMS’ expectation that cases be reported when they are decided and not when they are requested?
Elements:
 - C. Total number of PAs processed in the reporting period
 - F. Total number of UM exceptions processed in the reporting period
 - I. Total number of tier exceptions processed in the reporting period
 - L. Total number of formulary exceptions processed in the reporting period

Section X Redeterminations

Report Element A- Total number of redeterminations made in the reporting period- please clarify how these should be reported –should it be based on the date of the redetermination decision?

Section XI. Long-Term Care (LTC) Utilization and Waste For Element D:

D. For each network LTC pharmacy in the service area:

1. LTC pharmacy name;
 2. LTC pharmacy NPI;
 3. Contract entity name of LTC pharmacy;
 4. Chain code of LTC pharmacy;
 5. The total number of returned brand solid oral units (tablets, capsules, etc)
 6. The total cost of these returned brand drugs, where total cost should be calculated as gross drug cost (Ingredient cost + Dispensing Fee + Sales Tax)
 7. The total number of returned generic solid oral units (tablets, capsules, etc)
 8. The total cost of these returned generic drugs, where total cost should be calculated as gross drug cost (Ingredient cost + Dispensing Fee + Sales Tax)
-
1. We are concerned that plans currently do not have a way to track returns on elements 5-8. Plans do not directly contract with LTC facilities, thus will not have the authority to “require” LTC facilities to return unused medications to LTC pharmacies. Additionally, neither plans nor PBMs have a way to receive this type of information from LTC pharmacies or any other type of pharmacy. Specifically, currently there is no data or system that is able to support and capture the “return information” between LTC facilities and pharmacies and then trace a returned medication back to an individual processor (PBM) at the individual plan, beneficiary, and claim level. NCPDP returns standards will not be available until 2014.
 2. What will CMS do with the “chain code” value (e.g., are the ‘rolling up’ the data to ownership level to examine the patterns of returns by each owner of the chain? Additionally, which “chain code” value is to be used (NCPDP or Medco’s) in the reporting? Is “affiliation code” appropriate/needed for independents as CMS might be looking a network contract (versus ownership) patterns?
 3. Do the “cost” values include patient cost share (OOP cost of the ingredient) or only the plan’s share?
 4. Do LTC facilities include all but ALFs and then reporting on returns would only be for those claims paid as LTC (not retail as with an ALF)?

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Medicare Part D Reporting Requirements and Supporting Regulations under 42 CFR section 423.505 (CMS-10185)

Comment On: CMS-2010-0282-0001

Medicare Part D Reporting Requirements and Supporting Regulations under 42 CFR section 423.505 (CMS-10185)

Document: CMS-2010-0282-DRAFT-0003

CA

Submitter Information

Name: Cindy Lynch

Address:

Cerritos, CA, 90703

Organization: CareMore Health Plan

General Comment

The encounter data submission requirement should be for Medicare covered services only given the formats/forms of data CMS is requesting the data provided. Non Medicare covered services generally do NOT come in these formats and vary substantially between health plans. Our plan would incur an unfair level of administrative costs if required to provide this data in the requested formats.

The CMS submission error process needs to be revised for this (eg penalties for duplicate claim submission).

In order to optimize use of the data submitted, plans will need to send in information about their model of care, payment rules, adjudication procedures, etc. in addition to the data. These rules will obviously need to be regularly updated. We are concerned about the extra resources and costs associate with such a requirement.

Are lab results required to be included with the submission of lab claims? If so, this will result in more administrative costs and a different data format than requested.

Is the data submission on an incurred or paid basis?

How are interim bills handled? Are plans required to bundle first or will CMS do?

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CA

Submitter Information

Name: Cindy Lynch

Address:

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Organization: CareMore Health Plan

General Comment

With regard to the submission of all encounters, plans may possibly lose site of what's approved, etc. CareMore requests that Plans be provided with a matrix of what's being accepted and paid.

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none

Submitter Information

Name: Stephanie Bayer

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Organization: Universal American

General Comment

Reporting Requirements, Section XI, Subsection D.5-D.8 (page 19) are not currently feasible to report as these are not submitted/collected in any way as part of a submitted and/or reversed claim. Additionally, this methodology would still not account for drugs that are not returned, rather destroyed. Suggestion to remove this requirement until such time that NCPDP can include appropriate fields with the claim segment to capture this information.

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Medicare Part D Reporting Requirements and Supporting Regulations under 42 CFR section 423.505 (CMS-10185)

Document: CMS-2010-0282-DRAFT-0006

NY

Submitter Information

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Organization: Independent Health

General Comment

Section IV. Medication Therapy Management Programs – data element Q. Number of changes to drug therapy made as a result of MTM interventions. Changes include dosage changes, therapeutic or generic substitutions, and discontinuation of therapy.

The 2/28 reporting deadline does not allow for the most accurate picture of the data. For example, there can be many recommendations made to providers each month (including December) and it is not uncommon that responses to these recommendations indicate that the prescriber will discuss with the patient at their next visit. It is not uncommon for the next visit to be 3-6 months later, so complete change data would not be available until June of the following year for December recommendations.

Reporting timeline:

Argus Comment: The timeline requirements for the new data elements specific to waste reporting are overly aggressive given the industry has not defined a transaction to report waste. The industry has provided feedback to CMS through the review of CMS-4144-P. The feedback stated that return tracking should not be implemented until 2015 at the earliest.

For each network LTC pharmacy in the service area:

5. The total number of returned brand solid oral units (tablets, capsules, etc)

Argus comment: Please clarify where you would expect us to report brand drugs that are exempt from the 7 day dispensing requirement. For example if inhalers are exempt because they are in a package size that cannot be broken, should these still be reported under Brand?

6. The total cost of these returned brand drugs, where total cost should be calculated as gross drug cost (Ingredient cost + Dispensing Fee + Sales Tax)

Argus Comment: By including dispense fee and sales tax in the returned drug amount, the potential savings would be overstated. Return for destruction is not a refund. No crediting to plan will be done, therefore dispense fees and sales tax will not be credited. It is strictly the return of the drug and therefore the maximum potential savings would be the cost of the drug and a prorated amount of the sales tax at best (assuming it was never dispensed which is the ideal situation). It is unlikely that the dispense fee will be less therefore including the dispense fee in the estimated amount of savings would be overstating the potential dollars saved.

8. The total cost of these returned generic drugs, where total cost should be calculated as gross drug cost (Ingredient cost + Dispensing Fee + Sales Tax)

Argus Comment: By including dispense fee and sales tax in the returned drug amount, the potential savings would be overstated. Return for destruction is not a refund. No crediting to plan will be done, therefore dispense fees and sales tax will not be credited. It is strictly the return of the drug and therefore the maximum potential savings would be the cost of the drug and a prorated amount of the sales tax at best (assuming it was never dispensed which is the ideal situation). It is unlikely that the dispense fee will be less therefore including the dispense fee in the estimated amount of savings would be overstating the potential dollars saved.

9. By each NCPDP submission clarification code.

Argus Comment: Need to identify which submission clarification codes referenced. If referring to dispensing frequency, please state that you would like these reported by SCC (submission clarification code) that indicates the frequency of dispensing (i.e. 7 day)

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NY

Submitter Information

Name: Jeremy Laubacker

Address:

Buffalo, NY, 14221

Organization: Independent Health

General Comment

Revised Measure: Part C Grievances

CMS should consider excluding the timely notification reporting requirement for fraud grievances. This type of grievance does not have a timeframe for notification like other grievances do, and therefore does not make sense to report on this. Reporting total number of fraud grievances should be sufficient.

New Measure: Part C Enrollment/Disenrollment

These changes are significant. If an existing report from our enrollment vendor cannot accommodate these changes, then this would be a very manual report, and very cumbersome to report on.

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CMS Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10185 (OMB#: 0938-0992)
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-10185 (OMB#: 0938-0992)

Dear Sir or Madam:

I am writing on behalf of America's Health Insurance Plans (AHIP) in response to the Federal Register notice (75 FR 79000) published under the Paperwork Reduction Act on December 17, 2010, by the Centers for Medicare & Medicaid Services (CMS) providing an opportunity to comment on the Draft Medicare Part D Reporting Requirements for CY 2012. AHIP is the national association representing nearly 1,300 member companies providing health care coverage to more than 200 million Americans. The draft Part D reporting requirements are of significant interest to AHIP's member organizations, many of which participate in the Medicare Part D Prescription Drug Benefit (Part D) program. Our comments appear below.

SPECIFIC COMMENTS

Section I. Enrollment and Disenrollment

1. Enrollment

- + **Data Element M.** Data Element M proposes to require sponsors to report, of the total number reported in Element A, "the number of enrollment transactions submitted using the SEP Election Period code "S" related to change in residence."
 - The introductory language for this section of the reporting requirements indicates that CMS intends to collect data that are not otherwise available to the agency. However, sponsors are currently reporting to CMS through the enrollment process transactions associated with SEPs for changes in residence. Therefore, we recommend that CMS remove this data element from the proposed Part D Reporting Requirements.



- In addition, it appears that the reference to SEP Election Period code “S” is erroneous; it is our understanding that the SEP associated with changes in residence has been assigned its own Election Period code “V.” (See Plan Communications User Guide (PCUG) Appendices, page 140.)
- + **Data Elements Q., R., and S.** With the exception of Elements Q., R., and S., the descriptions of the data elements explicitly specify that they should be reported as a subset of either Element A. or C. It appears that a reference to Element A may be appropriate in Elements Q., R., and S. If this is correct, we recommend that the reference be added.

2. Disenrollment

- + **Data Element A.** Data element A proposes to require sponsors to report the total number of disenrollment requests received in the specified time period. (Emphasis added.) Use of the word, “requests,” appears to be in error because the instructions for this reporting section indicate that sponsors must report all disenrollments, which we interpret to mean both voluntary and involuntary disenrollments. However, involuntary disenrollments do not typically involve “requests.” For clarity, we recommend element A be revised to explicitly state that voluntary and involuntary disenrollment requests be reported.
- + **Data Element D.** Data Element D proposes to require sponsors to report, of the total number reported in Element A, the total number of disenrollments that were due to failure to pay premium. The instructions for this reporting section indicate that CMS will collect data on the elements that are “otherwise not available to CMS.” However, sponsors are currently reporting to CMS the disenrollment transactions associated with failure to pay premiums. (See PCUG Appendices, page H-106.) Therefore, we recommend that CMS remove this proposed data element from the Part D Reporting Requirements.

Section XI. Long-Term Care (LTC) Utilization and Waste

- **Data Element D.** Data Element D proposes several new items (specifically items 5-8) related to the reporting of the total number of returned prescription drugs and the total cost of the returned drugs for each network LTC pharmacy in the Part D sponsor’s service area. It is our understanding that there is currently no standard transaction for use by LTC pharmacies in reporting to the plan sponsor the drugs that have been returned from a LTC facility back to the pharmacy. Accordingly, we recommend that CMS delay implementation of the proposed new items 5-8 of Element D. under this section of the reporting requirements until a suitable standard has been developed by NCPDP.

February 15, 2011
Page 3



We have appreciated the opportunity to comment. Please contact me if additional information would be helpful or if you have questions about the issues we have raised. I can be reached at (202) 778-3209 or cschaller@ahip.org.

Sincerely,

A handwritten signature in cursive script that reads "Candace Schaller". The signature is written in black ink and has a long, horizontal flourish at the end.

Candace Schaller
Senior Vice President, Federal Programs

Comments on Proposed Plans for Collection of Encounter Data From Medicare Advantage Organizations

Form Number: CMS-10340 (OMB #:0938-New);
Name of Commenting Organization: SNP Alliance
Contact Person: Richard Bringewatt
Email: rbringewatt@nhpg.org
Phone: 202-62-1516

The following comments are made in response to proposed Part C Medicare Advantage (MA) Reporting Requirements and Supporting Regulations as communicated in the Federal Register/Vo. 75, No. 242/Friday, December 17, 2010. These comments are made with the assumption that beginning January 2012, CMS intends to collect encounter data for Medicare Advantage (MA) organizations to be used for “determining the risk adjustment factors for payment, calibrating the risk adjustment model, calculating Medicare DSH percentages, Medicare coverage purposes, and quality review and improvement activities.” We also understand that CMS is asking for comments on the following issues:

1. The need for the information collection and its usefulness in carrying out the proper functions of the agency.
2. The accuracy of CMS’ estimate of the information collection burden.
3. The quality, utility, and clarity of the information to be collected.
4. Recommendations to minimize the information collection burden on the affected public, including automation collection techniques.

General Comments

While the SNP Alliance understands CMS’s interest in capturing more information about ongoing practice, and the potential for using encounter data to improve risk adjustment and to help address a variety of other proposed uses, we are concerned about:

1. The pace of implementation without commensurate timely guidance from CMS.
2. The significant additional costs that will be incurred by health plans, particularly for smaller plans and those with a higher level of care complexity, without evidence of added value.
3. The absence of clarity about the methodology that CMS will use to calibrate risk adjustment and the absence of information about plans for other cited uses.
4. The potential for further delay in CMS efforts to “*evaluate and revise the HCC risk adjustment system in order to, as accurately as possible, account for higher medical and care coordination costs associated with frailty, individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness, and also to account for costs that may be associated with higher concentrations of beneficiaries with those conditions,*” as required by Congress.

We are particularly concerned about the growing, disproportionate regulatory and reporting complexities and costs accruing for plans seeking to specialize in care of poor, frail, disabled, and/or seriously ill beneficiaries—Medicare’s most vulnerable, fast-growing, and high-cost service groups.

The timeframe for implementation is extremely aggressive.

Plans are awaiting final encounter data requirements and training for this project. More detailed requirements are needed by plans to initiate development of their encounter data systems. Further delays in accessing the detailed requirements will make it very difficult to meet the current timeframe. We understand that plans need at least 12-18 months to implement the system after full information and technical resources become available. This not only creates significant time pressures for plans but many plans did not have sufficient information to include additional needed costs in their 2011 bids. A number of plans are also concerned about the added complexity and costs associated with implementing this new system under the ICD-9 coding system when the ICD-10 system will be implemented shortly.

Recommendation: CMS should reevaluate its current timeframe for implementation in light of these concerns and make appropriate changes in schedule to ensure for a smooth transition that reduces the potential for system-induced error and unnecessary additional costs.

There has been some inconsistency in verbal and written communication from CMS that needs clarification. For example—

1. **Encounter Data Submission Frequency.** Page 6 & 7 of the Notice indicate that encounter data must be submitted at least weekly while the National Encounter meeting and subsequent workgroup handouts indicate submission will occur at least monthly.

Recommendation: We request that data be submitted on a monthly basis.

2. **Collection Frequency (Page 7, section 6).** The Notice indicates that the final submission deadlines would be similar to those for the risk adjustment data. The National Encounter meeting and subsequent workgroup meetings have discussed shortening the final submission deadline.

Recommendation: We recommend maintaining the existing risk adjustment timeline to allow providers to submit claims to health plans within their allowed timelines, and for the plans to process these claims.

3. **Pricing Information:** The Notice does not specify what type of payment information will be required.

Recommendation: FIDESNPs suggested submitting total Medicare and Medicaid payments on claims on a workgroup call and CMS concurred. We request confirmation of this approach. We also request clarification of whether total payment should also be submitted by DSNPs that provide some but not all Medicaid benefits; i.e., should all Medicare and Medicaid payments be included in the claim submission?

4. **Scope of Encounter Data Submission:** CMS initially suggested that plans submit all adjudicated claims/encounters. In subsequent discussion, CMS indicated that CMS would edit the encounter data against the NPPES files for a valid NPI. If CMS uses a front-end edit to the encounter data system, instead of when the data are extracted to feed the risk adjustment system, we understand atypical provider data will be excluded

from CMS's system. While this would not affect risk adjustment, since atypical providers are not allowable provider types, the exclusion would under represent the true costs of serving duals. Plans have also noted that providers do not always update their information on the NPES files. Thus, the information plans are receiving on a claim may coincide with what is on the NPES files. This may affect the collection of illness burden data, as well as further suppress the cost of serving the population.

Recommendation: If CMS is interested in obtaining a comprehensive picture of total dual costs, all data should be captured in some manner. We think this information would be of significant interest to policymakers and would be important information for CMMI and FCHCO as they develop methods for benchmarking dual demonstrations.

The potential burden of implementation appears to be more severe for plans that specialize in care of complex care beneficiaries.

1. Unlike fee-for-service providers, staff model plans and plans with capitated provider networks do not always generate claims.

There is considerable evidence that care of persons with multiple, complex, ongoing care needs require a closer and ongoing working relationship with beneficiaries and their families, as well as with multiple care providers. As a result, a number of specialty care programs have chosen to become more actively involved in primary care and related care management functions for high-risk beneficiaries. With an encounter system rooted in claims data, this creates new complexity for plans that either provide services directly or contract with providers in ways that do not generate claims as they do for providers paid under fee-for-service.

Recommendation: We request that CMS consider establish a simplified policy for staff model plan or plans functioning as a plan/provider hybrid in order to provide CMS with needed data without unnecessarily burdening these plans or requiring them to change practices that have proven to be more effective in serving high-risk populations.

2. Small plans. While some would suggest that the additional burden experienced by small plans in seeking to respond to new encounter data requirements provides further evidence that small plans should either merge or become program components of other larger plans, there is increased evidence that under certain circumstances, smaller plans are more able to maintain ongoing relationships important in care of high-risk populations. PACE, Institutional SNPs, and Dual SNPs that exclusively serve persons who are nursing home certifiable are examples of plans that have proven themselves to be not only high quality programs but financially viable at enrollment levels deemed too small for general MA plan populations. A plan's ability to respond to increased administrative burdens should not be the determining factor for defining optimum plan size. Rather, a plan's overall effectiveness in serving a defined population should be the primary factor.

Some small plans are particularly concerned about the backend processes that will require significant additional resources and systems to manage. The proposed encounter data requirements will most likely result in smaller plans having to create an

entirely new operational business unit to manage; and in some cases they will need to design an entirely new business function.

Recommendation: We request that consideration be given to providing additional support to small plans, extending the timeframe for their compliance, or reducing the complexity of the requirements for small plans.

- 3. Plans responsible for Medicare AND Medicaid services for dual beneficiaries.** A key concern for plans with contracts for Medicaid services is that CMS is implementing a new encounter data reporting system without coordinating this effort with state requirements for encounter data reporting. This is not only going to result in significantly higher costs and unnecessary administrative complexities for dual plans focused on advancing integration, in any form; but it will further bifurcate the administration of Medicare and Medicaid programs for duals at the very time that CMS is advocating for full integration through the Center for Medicare and Medicaid Innovation. This is not only true for programs that may evolve under *new* demonstration authority but for plans that have long-standing practices established through *prior* demonstration authority.

Recommendation: Work with FCHCO, fully integrated plans, and States advancing fully integrated care programs to establish an integrated policy and approach for addressing the interface between Medicare and Medicaid for SNPs that have Medicaid contracts. This needs to occur for ALL SNPs with Medicaid contracts and not just for those that may evolve under new demonstration authority.

- 4. Plans with a high percentage of persons with multiple, complex and ongoing care needs.**

Since data reporting will be based on a much larger set of variables and new data validation requirements will be imposed based on physician taxonomies, it will be much more challenging for plans to validate data from multiple providers serving persons with multiple chronic conditions who frequently see 15 or more unique physicians per year, with multiple encounters throughout the year. The sheer volume of encounters to manage will not only increase their average PMPM cost for compliance and curing deficiencies, but exposes them to potential fraud and abuse challenges that are related more to unintentional administrative error than to any intent to deceive or do harm.

SNPs already have a significantly greater data burden than standard MA plans as a result of existing additional reporting requirements for HEDIS and for structure and process measurement. They also have higher clinical and administrative costs related to Model of Care requirements, including the expectation that SNPs provide add-on services and benefits to address special needs. Additional administrative requirements were added this year by the SNP approval process mandated by the ACA. The accumulation of additional data burden above and beyond that required for standard MA plans is beginning to threaten the financial viability of specialized managed care. This is particularly true for small plans with limited IT and resources.

Recommendation: Work with the SNP Alliance to evaluate and revise encounter data requirements to account for the added complexities of compliance for plans with higher concentrations of beneficiaries with higher medical and care coordination costs and

more complicated encounter management problems related to care of frail elders; adults with disabilities; persons with complex medical conditions; and individuals with a diagnosis of mental illness.

There is a great deal of uncertainty about the relative value of using encounter data for determining the risk adjustment factors for payment and calibrating the risk adjustment model for plans that have higher concentrations of frail elders, adults with disabilities, and other persons with complex medical conditions.

The SNP Alliance continues to have concerns about the adequacy of HCC risk adjustment methodology for plans specializing in care of persons who are dually eligible for Medicare and Medicaid and for those who are frail, disabled, and with complex medical conditions. Without greater knowledge about the encounter data methodology to be used in determining the risk adjustment factors for payment and calibrating the risk adjustment model for plans that specialize in care of persons with unique and complex care needs, it is difficult to provide meaningful comment on CMS's stated primary purpose of implementing a new encounter data system.

Recommendation: We strongly encourage CMS to proceed as quickly as possible with evaluating whether the current risk adjustment methodology "fully accounts for the medical and care management costs of persons associated with frailty, individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness, and also accounts for costs that may be associated with higher concentrations of beneficiaries with those conditions," as required by the Affordable Care Act. We also request that CMS consider allowing plans to maintain a chronic diagnosis from year to year, once verified and accepted by CMS, to reduce the risk of diagnostic codes being inadvertently dropped, resulting in an inappropriate reduction in risk score and payment. In addition, we request that CMS provide Special Needs Plans with information, as soon as possible, about its plans for using encounter data to calibrate the risk adjustment model so that plans can appropriately evaluate and prepare for its potential effects on specialized managed care programs.