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To: Centers for Medicare & Medicaid Services (CMS),
Office of Strategic Operations and Regulatory Affairs,
Division of Regulations Development
CMS-10137 (OMB #0938-0936) and CMS-10237 (OMB #0938-0935)
Submitted via www.regulations.gov

From: Barbara Reid
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Date: August 30, 2011

Re: 1. CMS–10137 (OMB # 0938–0936); Application for Prescription Drug Plans (PDP); Application for Medicare Advantage Prescription Drug (MA–PD); Application for Cost Plans to Offer Qualified Prescription Drug Coverage; Application for Employer Group Waiver Plans to Offer Prescription Drug Coverage; Service Area Expansion Application for Prescription Drug Coverage
2. CMS–10237 (OMB # 0938– 0935); Part C Medicare Advantage and 1876 Cost Plan Expansion Application

We have reviewed the collections listed above in response to the notice published under the Paperwork Reduction Act in the July 1, 2011 Federal Register (76 FR 38656) and provide the attached comments.

These comments are provided on behalf of UnitedHealthcare Medicare & Retirement and other UnitedHealth Group affiliates, including UnitedHealthcare Community & State, that manage Medicare Advantage and Part D business (collectively "United").

We greatly appreciate the opportunity to comment, and we look forward to continuing to work with CMS to develop successful products and services for Medicare beneficiaries. If you have any questions or concerns on our comments, please contact me at 715-832-5235 or via email at barbara_reid@uhc.com.

Draft CY2013 Applications

Comments Submitted by
UnitedHealthcare/UnitedHealth Group
August 30, 2011

MA-PD and PDP Service Area Expansion (SAE) Application

1. Review of MAO Expansion Applications, *Application for MA-PD and PDP Service Area Expansion (SAE)*

United appreciates the opportunity to comment on CMS' draft 2013 applications and the transparency that the review and comment process affords to managed care organizations. We believe that this same transparency should extend to CMS' process for review of MAO expansion applications. For example, while section 1.1 of the application notes that when CMS denies an application, plans have the right to appeal as provided by 42 C.F.R. 422, subpart N, it does not detail the criteria that CMS will use to review expansion applications, or the notice that CMS will give to plans explaining the basis for any expansion denials. Our concerns regarding CMS' review process include but are not limited to the following:

- As part of its review, CMS assesses the applicants past performance using a methodology ("Methodology") outlined in a December 12, 2010 memorandum, guidance that has not been subject to the comment process, nor part of a routine regulatory promulgation.
- The Methodology attributes the performance of a single poor performing contract to all other contracts held by the Applicant. As a result, high performing contracts may be denied expansion based solely upon the poor performance of a single outlier contract held by the same legal entity.
- The Methodology unfairly and disproportionately impacts those plan sponsors that provide items and services under a single, licensed entity to the greatest number of Medicare beneficiaries.
- The Methodology fails to take into account the unique characteristics of Special Needs Plans (SNPs) and as a result unfairly and disproportionately impacts those plan sponsors who provide SNPs that provide services to Medicare's most vulnerable beneficiaries.
- The Methodology is applied in a manner that fails to give plan sponsors sufficient notice of how the past performance point system was applied to their specific applications. In order for the Applicant's appeal to be meaningful, CMS should provide an explanation of the performance score and how it was calculated.

Part C - MA, New MA-PD and New PDP Applications

2. Information Available Upon Request, *Attestation #4, Part C - MA Application, Sect. 3.12 A., p 39, New MA-PD Application, Sect. 3.14 A., p 80, New PDP Application Sect. 3.13 A., p 75*

Attestation # 4 does not match the Medicare Managed Care Manual (MMCM) Guidelines in Chapter 3, section 30.11. The attestation reads that certain information must be available "upon request" and the Guidelines indicate that some of the information listed in the attestation must be included in the enrollment materials. To ensure consistency with previously released CMS guidance, we suggest updating the attestation to clarify which materials must be made available upon request and which must be included in the enrollment materials as required by MMCM Chapter 3, section 30.11.

New MA-PD and New PDP Applications

3. Telehealth as Interactive Person to Person Consultation, *New MA-PD Application, Sect. 3.2.4 A. #6, p 50; New PDP Application, Sect. 3.2.4 A. #6, p 50*

The Medication Therapy Management (MTM) Section, attestation #6 defines the requirements for the annual Comprehensive Medication Review component of MTM to include an interactive, person-to-person, or telehealth consultation by a pharmacist or qualified provider. Chapter 7, Section 30.3 of the CMS Prescription Drug Benefit Manual provides for interactive methods such as the telephone.

We recommend that the second bullet-point of the attestation be revised as follows to come into line with the CMS guidelines. The change is indicated by italics. "An annual comprehensive medication review (CMR) with written Summaries. The CMR must include an interactive, person-to-person, or telehealth *(including telephone)* consultation performed by a pharmacist or other qualified provider unless the beneficiary is in a long-term care setting. This interaction may be face-to-face or through other real-time interactive methods such as the telephone. The Summary resulting from the CMR must comply with the requirements for a standardized format as specified by CMS, and…"

Part C – MA Application

4. Fiscal Soundness *Part C - MA Application, Sect. 3.7 A., #2, p 29*

In the Fiscal Soundness Section, attestation #2 states: "Applicant is in compliance with all State requirements and is not under any type of supervision, corrective action plan, or special monitoring by the State regulator."

We assume that this attestation is focused on complying with financial requirements, since Section 3.3, attestation #4 addresses supervision, corrective action plan, or special monitoring by the State regulator in general. If that is correct, we recommend that this attestation be revised to clarify that it only refers to financial requirements.

For example, we recommend this attestation be revised as follows: Applicant is in compliance with all State requirements and is not under any type of supervision, corrective action plan, or special monitoring by the State regulator *with respect to financial requirements.*

5. Response to Calls Received via Alternative Technology, *Part C - MA Application, Sect. 3.12 A., #10, p 41*

Attestation # 10 requires that calls received via alternative technology must be acknowledged within 24 hours of receipt. The CMS MMCM Guidelines at Chapter 3, Section 80.1 provides for "no more than one business day." The 24-hour requirement in the attestation does not account for calls received on weekends and holidays. We recommend updating the attestation to correctly reflect the requirement of acknowledgement in "no more than one business day."

6. Notice of Acceptance or Denial of Claims Payment, *Part C - MA Application, Sect. 3.14 A., #3, p 45*

Attestation #3 states that "Applicant will give the beneficiary prompt notice of acceptance or denial of a claims' payment in a format specified by CMS."

CMS rules do not require that plans provide notice of claim acceptance when there is no cost share involved (except for PFFS claims). There is also no requirement to notify beneficiaries of claim denials when the claim only involves provider reimbursement (such notices would be confusing to beneficiaries). Rather, the requirement is that when a claim is denied resulting in member liability, plans must provide the member with his or her appeals rights. We suggest an addition to the attestation that explains that the notice is required in all cases where there is cost-sharing or member liability.

For example, we recommend that this attestation be revised as follows: Applicant will give the beneficiary prompt notice of acceptance or denial of a claims' payment in a format specified by CMS *in all cases where there is member cost-sharing or member liability.*

7. Development of Claims, *Part C - MA Application, Sect. 3.14 A., #4, p 45*

We believe that the addition of the word "complete" in this attestation will more closely align with CMS requirements to develop complete claims and process all claims promptly. We recommend that the attestation be revised by inserting the word "complete," as follows:

"Applicant will comply with all applicable standards, requirements and establish meaningful procedures for the development of complete claims and processing of all claims including having an effective system for receiving, controlling, and processing claims actions promptly and correctly."

8. Agreements with State Medicaid Agencies, *Part C - MA Application, Appendix 1, Specific Requirements for Dual Eligible SNPs, p 91*

We encourage CMS to continue providing flexibility with the deadlines by which D-SNPs are required to have completed the agreements with State Medicaid Agencies. The current draft of the application does not specify specific submission deadlines and we encourage CMS to remain consistent with this approach.

9. Designation of D-SNPs, *Part C - MA Application, Appendix 1, p 91*

The new SNP Chapter (16B) states "New D-SNPs must be classified as either "Medicaid subset $0 cost share" or "Medicaid subset Non-$0 cost share." To avoid confusion, we recommend:

a. Define "Medicaid subset Non-$0 cost share."
b. Clarify whether existing Dual SNPs with contracts in place for CY2012 with Medicaid Agencies may continue with their existing designation (e.g., Full Dual, All Dual, Zero Cost Share, etc.) or whether a new designation will be needed for 2013.
c. Clarify whether existing Dual SNPs without Medicaid Agency contracts in place for CY2012 may continue with their existing designation or whether a new designation will be needed for 2013.
d. Clarify whether the newly created D-SNP for 2013 and future years must be classified as "Medicaid subset $0 cost share" or "Medicaid subset Non-$0 cost share."

In summary, we recommend adding a definition for "Medicaid subset Non-$0 cost share" as a Dual SNP that can enroll all categories of Duals or any defined subset of duals as documented in the agreement with the State Medicaid Agency. We also recommend providing clarification on how Medicare Advantage Organizations (MAOs) should designate D-SNPs for purposes of the 2013 applications.

10. SNP Specific Attestations, *Part C - MA Application, Appendix 1, Sect. 11, Staff Structure and Care Management Roles, p 103*

Under the "Staff Structure and Care Management Roles" category, there are several items that are general health plan operational items not unique to SNPs (e.g., process claims). We recommend that CMS remove attestations of general operational duties applicable to all types of plans so the "Staff Structure and Care Management Roles" category is more focused on items applicable to SNP plans.

11. Notifications to Interdisciplinary Care Team, *Part C - MA Application, Appendix 1, Sect. 11, Provider Network and Use of Clinical Practice Guidelines, #51, p 107*

Under the "Provider Network and Use of Clinical Practice Guidelines" category, item #51 states, "Applicant has written procedures that require notification to the interdisciplinary care team and respective providers when transitions of care occur." However, it is not necessary to always notify all members of the interdisciplinary care team. We recommend that #51 be changed to read, "Applicant has written procedures

that require notification to *appropriate* members of the interdisciplinary care team and respective providers when transitions of care occur."

12. Transition of Care Analysis, *Part C - MA Application, Appendix 1, Sect. 11, Provider Network and Use of Clinical Practice Guidelines, #53, p 107*

Under the "Provider Network and Use of Clinical Practice Guidelines" category, item #53 states, "Applicant tracks and analyzes transitions of care to assure timeliness and appropriateness of services." There is concern that some providers will serve a very small number of SNP members and it will be difficult for them to give us updates on care transitions, which may impact transition of care analysis.

We recommend that #53 be changed to read, "Applicant analyzes transitions of care and identifies area of improvement to meet member needs." With these changes, this item may fit better with the quality improvement sections of the application.

13. Periodic Surveillance of Providers, *Part C - MA Application, Appendix 1, Sect. 11, Provider Network and Use of Clinical Practice Guidelines, #59, p 107*

Under the "Provider Network and Use of Clinical Practice Guidelines" category, item #59 states, "Applicant conducts periodic surveillance of employed and contracted providers to assure that nationally recognized clinical protocols and guidelines are used when available and maintains monitoring data for review during CMS monitoring visits." This statement implies that the applicant will need to conduct surveillance of all providers. This raises concerns about applicability to a broader provider network that can be several thousand providers. Unless a sampling methodology is allowed, surveillance of a larger provider network would be administratively burdensome and we do not believe this is what CMS intended given use of the terms "periodic" and "surveillance." We recommend that this section be modified so that use of a sampling methodology is allowed for the periodic surveillance of providers.

14. Web-based Data, *Part C - MA Application, Appendix 1, Sect. 11, Health Risk Assessment to Communication Systems, #25, p 110*

Under the Health Risk Assessment to Communication Systems section, plans are required to attest that their communication systems "include some or all of the following: 25. Web-based database." We believe this is a typographical error and recommend changing #25 to state "Web-based *data*."

15. Services vs. Care Management Services, *Part C - MA Application, Appendix 1, Sect. 11, Care Management for the Most Vulnerable Subpopulations, #2, p 110*

Under the "Care Management for the Most Vulnerable Subpopulations" category, item #2 states, "Applicant delineated additional services it will provide for its most vulnerable beneficiaries. These add-on services address the specialized needs of the following vulnerable special needs individuals within each target population." We recommend

changing "services" to "care management services" because SNPs do not provide a different set of benefits for members designated "most vulnerable."

16. Stakeholders, *Part C - MA Application, Appendix 1, Sect. 11, Performance and Health Outcome Measurement, #29, p 111*

Under the "Performance and Health Outcome Measurement" category, item #29 states, "Applicant communicates the results of its model of care evaluation to all stakeholders as identified by the CMS and SNP." It is not clear what stakeholders CMS will be identifying. We recommend that the reference to CMS be removed and this item read "Applicant communicates the results of its model of care evaluation to all stakeholders identified by the SNP."

17. Completion of Section 14 or 15, *Part C - MA Application, Appendix 1, Sect. 14, 2013 D-SNP State Medicaid Agency Contract Upload Document and Sect. 15, C-SNP State Medicaid Agency Contract Matrix, pp 114-117*

It is unclear whether Section 14 or 15, or both, should be completed by applicants.

In addition, the top of Section 14 includes a note that reads "Note: Complete this section if the applicant is currently in contract negotiations with the State to amend or update an existing contract for the application year." This note should be broadened to include applicants negotiating initial contracts with Medicaid Agencies (not just amendments or updates to existing contracts).

We recommend that CMS provide clear directions regarding the circumstances under which each of these two sections need to be completed. Please clarify that Section 14 is to be completed if contract negotiations are in progress (for new contracts or amendments to existing contracts) and Section 15 is to be completed if the State Medicaid Contract has already been signed. Further, please clarify that applicants need only complete section 14 or 15 as appropriate.

18. Coordination of Benefits, *Part C - MA Application, Appendix 1, Sect. 14, 2013 D-SNP State Medicaid Agency Contract Upload Document, #3, p 115*

Under the 2011 D-SNP State Medicaid Agency Contract Upload Document, item #3, bullet #3 states, "Third party liability and coordination of benefits." We believe that clarity is needed with regard to the meaning of "third party liability." We recommend that reference to "third party liability" be removed because CMS has not provided clear direction as to what is meant by this. As an alternative, please clarify or provide background on "third party liability" in this context.

19. Provision of Medicaid Services, *Part C - MA Application, Appendix 1, Sect. 14, 2013 D-SNP State Medicaid Agency Contract Upload Document, #5, p 115*

Under the 2011 D-SNP State Medicaid Agency Contract Upload Document, item #5:

a. There is a significant amount of confusion for both D-SNPs and State Medicaid Agencies as to whether the State Medicaid Agency contract requires the D-SNP to provide Medicaid services. Please clarify that the provision of Medicaid benefits is not always required and that increased levels of agreed-upon coordination of Medicaid benefits is also acceptable.
b. Specifically, the NOTE comment only makes reference to Medicaid services "that the organization is obligated to provide under its State contract," which is confusing without a reference to coordination of services as another alternative.

We are assuming that this section would only be included if the State Medicaid Agency contract requires the D-SNP to provide Medicaid services. Broadly, if State Medicaid Agencies and MAOs determine that increased coordination will best serve dually-eligible members, the requirements should be clarified to allow such. Specifically, in item #5 and elsewhere in the document where providing Medicaid benefits is referenced, please clarify that agreed-upon coordination is acceptable.

20. Network Adequacy Standards, *Part C - MA Application, Appendix 1, Sect. 14, 2013 D-SNP State Medicaid Agency Contract Upload Document, #7, p 115*

Under the 2011 D-SNP State Medicaid Agency Contract upload document, item #7, the Note states "The description must contain language indicating that the MA SNP has written procedures for ensuring Medicaid network adequacy including access standards." The applicability of Medicaid network adequacy standards is confusing if the State Medicaid Agency Contract only provides for the coordination of Medicaid services and not the actual provision of services.

Please clarify in the Note for item #7 that this item is only applicable if the State Medicaid Agency contract requires the D-SNP to provide Medicaid services.

21. Facility and Medicare Numbers, *Part C - MA Application, Appendix 1, Sect. 16, I-SNP Upload Document, #2, p 118*

The I-SNP Upload document, #2, requests the Medicaid number of the facility and a Medicare number. Are both numbers needed? Please clarify for the I-SNP Upload document sections that require lists of contracted facilities whether the Medicare or Medicaid number is being requested.

Provider Table

22. Oral Surgery Specialty, *Provider Table*

The Oral Surgery specialty was not counted towards adequacy for 2012. Although the 2013 HSD Instructions include the Oral Surgery specialty code, will this specialty again not count towards adequacy for 2013? Please clarify.

Provider and Facility Table

23. County Classifications, *Provider and Facility Tables*

For Large Metro and Metro counties that in addition to one or more urban centers also contain large rural areas where physicians are not available (forests, reservations, military bases, etc) and the number of Medicare beneficiaries is low or non-existent in these areas, we suggest CMS consider adjusting the criteria either by using a lower level county classification or by lengthening the distance standards for certain specialists in those geographically challenged counties to better compensate for these geographical differences within a county.

Facility Table

24. Distance Requirement for Laboratory Services, *Facility Table*

CMS distance requirements for Laboratory Services are the same in Large Metro (5 miles) & Metro (10 miles) as they are for PCP distance requirements. However they differ from Acute Inpatient Hospital distance requirements which are: Large Metro 10 miles (versus 5) and Metro 30 miles (versus 10). Many times hospitals can not be used for their Laboratory Services based upon this differentiation.

Many enrollees are not seen at independent labs for their lab draws. They are however seen at their PCP or specialist's office (or at hospitals or drawing stations), where specimens are then sent to laboratories for processing. It is our recommendation that minimum time/distance requirements be removed for Laboratory services since the point of contact for those services are available at PCP, specialist or hospitals in addition to independent labs and drawing stations.

25. Formatting of Available Data, *Facility Table*

CMS requires information that is not readily or easily available for use in an automated fashion. For instance, the number of Medicare certified beds for hospitals, SNFs, ICUs and MH facilities is not readily available to Managed Care Organizations (MCOs). This is also true of Medicare certification numbers. For the categories of Cardiac Surgery, Cardiac Catheterization, Outpatient Infusion Chemo, Mammography, and Outpatient Dialysis more defined instructions on how to use medicare.gov or downloadable files would help.

We believe that CMS' requirements for certain data is administratively burdensome. Therefore, we request that CMS provide certain information in excel format or other downloadable data file formats that will assist plans in their automated production of HSD tables and population of these fields with accurate CMS information. For example, CMS could provide a resource from which MCOs can obtain Medicare Certification numbers, bed counts, etc. Currently, Medicare.gov does not provide downloadable files of providers performing these services. We recommend CMS provide instructions on

using Medicare.gov or other sites (such as FDA MQSA files) so that reviewers and plans are using the same files to determine availability of services. Likewise, we recommend that CMS issue clear definitions of these services to help ensure that organizations are consistent in their reporting of these categories.

26. Where Services are Provided, *Facility Table*

Some services like Outpatient Infusion Chemo may be provided by Medical Oncologists in their offices. We recommend CMS provide clarification regarding whether services on the Facility Table may be provided by providers listed on the Provider Table.

27. Medicare Certified Bed Count Source, *Facility Table*

The AHA specifies total adult medical/surgical beds, but not Medicare certified beds. The AHD provides Medicare certified beds, but summarizes counts by hospital system versus by hospital. If there is no CMS standard file used for bed counts, health plans cannot be consistent with how this information is supplied. Data could vary by health plan and by resource.

We recommend CMS clarify which source(s) CMS uses for Medicare Certified Bed counts (Acute Inpatient, ICU, SNF & IP Psych).

HSD Instructions

28. Accessibility Criteria, *HSD Instructions*

a. In some cases a service or specialty access may reach close to the 90% standard. We recommend CMS consider utilizing rounding in the accessibility criteria and provide guidance in the HSD instructions to that effect.
b. For some specialties there is a struggle with meeting both of CMS' time and distance requirements. We recommend CMS consider health plans as meeting criteria if at least one of the criteria (time OR distance) is met. For example, geographical terrain in rural areas impedes meeting criteria requirements.

29. Review of Specialty Type, *HSD Instructions*

Medicare.gov is a main source of truth for plans in terms of comparison of their networks. We recommend CMS consider allowing plans to review providers based on specialty type in excess of a 25 mile range. If allowed, we recommend CMS update the web site to offer searching criteria beyond the 25 mile range.

30. Errors in Participating List of Providers, *HSD Instructions*

Oftentimes, a service or provider that is posted to Medicare.gov as being Medicare participating is, in fact, verified by the plan as not participating or does not perform the services listed. For example under Oral Surgery, Medicare.gov may list a general dentist

as performing oral surgery. However, when contacted, that dentist informs us they do not perform oral surgery. Yet the network is being evaluated against the Medicare.gov standard of availability of oral surgery. With Outpatient Dialysis, Medicare.gov may list services available at an Acute Inpatient Hospital, yet the hospital operating certificate is not approved by DOH to provide those services.

Please clarify how plans are to address network adequacy in situations where a provider does not perform the services listed in Mecdicare.gov or a provider is posted in Medicare.gov as participating in Medicare but is verified as not participating.

31. Provider Signatures, *HSD Instructions*

Applicants are required to provide a template of provider signatures when the HSD tables already contain this required information. We believe that providing the signature page form is duplicative of information that organizations are already required to provide. We wish to avoid duplication since signature pages have been collected using existing HSD tables or the data can also be found on existing HSD tables.

The 2013 form has several fields requesting information already on the HSD tables: Name of Physician/Provider, Type (MA Provider/Facility Tables), Name of Contract Template Type (MA Contract and Signature Index - Provide/Facilities), Name of Signatory to Contract (MA Signature Authority Grid), and a field for Date Contract Signed when this is on the signature page itself. We recommend that the Signature Page Form requirement be eliminated.

32. Exception Form – Distance from Beneficiaries, *HSD Instructions, Exception Form: CMS Exception form required for 2013 - DISTANCE FROM BENEFICIARIES (Based on Sample Beneficiary File in HPMS) versus modified version used for 2012 - DISTANCE FROM BENEFICIARIES (Based on Population Center)*

For exceptions, we calculated DISTANCE FROM BENEFICIARIES Based on Population Center because it is a simpler, easier, less resource intensive method of determining accessibility. This approach also makes more sense in the case of an I-SNP where a population center would be the contracted SNF where the beneficiaries reside and not where MA eligibles are distributed throughout the county. If CMS requires distances be based on eligibles distributed throughout the county rather than population centers, we ask that CMS provide clarity and direction on how they want health plans to use the Sample Beneficiary file along with detailed instructions on how CMS is calculating distances.

33. Dating of Documents

Not all document revisions posted to the http://www.cms.gov/MedicareAdvantageApps/ website are dated in the naming convention. Including a date in the naming convention would help plans to determine that files downloaded from HPMS are the most current and the same as those posted on the CMS website.

34. Release of HSD Tables Prior to Final Release of Final Applications in Early January, *HSD Instructions*

While it is recognized and appreciated that CMS has provided the draft HSD tables early, it is requested that the final HSD Tables and HSD Instructions be made available by November or December rather than with the release of the final applications in early January. This would allow organizations with a high volume of submissions additional time to train network personnel and sufficient time to upgrade HSD tools, excel formulas, etc. with any changes made to the tables.