**Date:** 2/23/2016  
**Disease State:** Chronic Kidney Disease  
**Therapeutic Area:** Renal  
**Area of Interest:** Chronic Kidney Disease  

**Internal Requestor Information:**  
Name: Nancy Kelly  
Title: Manager, Medical Education and Communication  
Sanofi Renal  
Phone: 617-591-5698  
E-Mail: nancy.kelly@sanofi.com  

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**Chronic Kidney Disease Treatment Gap**

According to the National Kidney Foundation 26 million adults in the US have chronic kidney disease (CKD) with many others at increased risk for the disease. *(Ref. 1 JAMA)*. High risk factors include diabetes, a family history of kidney disease, and high blood pressure. If the disease progresses there is the potential for kidney failure requiring dialysis or a kidney transplant *(Ref. 2 NKF)*.

The Centers for Disease Control and Prevention identify that the risk for developing CKD increases with age and is more widespread in the 70 years and older population. The CDC’s “National Chronic Kidney Disease Fact Sheet, 2014” recognizes other risk factors as obesity. It is common for those in the early stages of CKD not to recognize the symptoms, but once the disease is diagnosed lifestyle changes and medications can help manage the condition. Early detection and treatment is critical in preventing the progression of this disease *(Ref. 3 CDC)*. The rising incidence and prevalence of chronic kidney disease means primary care clinicians will be seeing and managing it more. Fortunately, there are good tools available which allow better understanding for patients and clinicians on how to best manage their disease.

Chronic kidney disease is the progressive loss of kidney function over time. As kidney function declines, mineral homeostasis deteriorates. This is accompanied by a disturbance of normal serum and tissue concentrations of phosphorus and calcium as well as changes to circulating levels of hormones, including parathyroid hormone (PTH), 25-hydroxyvitamin D, 1,25-dihydroxyvitamin D (1,25 D), and other vitamin D metabolites; fibroblast growth factor-23 (FGF-23); and growth hormone. These changes result in the kidney’s inability to maintain appropriate levels of calcium and phosphorus, causing abnormal bone hormone levels, termed mineral and bone disorder or CKD-MBD. *(Ref 4. NIDDK 2009; Ref. 5 Raggi 2010)*

Patients with CKD-MBD are at higher risk for CV morbidity and mortality due to inadequate management of MBD abnormalities. *(Ref. 6 Goldsmith 2010)*

Only 68% of nephrologists and only about 43% of cardiologists, NPs, and nurses recognized that phosphate binders have a role in management of hyperphosphatemia in predialysis CKD. Only 60% of nephrologists and only about 40% of cardiologists, NPs, and nurses knew that non-calcium based phosphate binders are associated with decreased mortality compared with calcium based phosphate binders.

Learning Gap: The relationship between CV morbidity and mortality, calcium and phosphorous balance, and long-term effects from treatment options for MBD in patients with CKD is poorly understood by many clinicians who manage these patients.
Sanofi is seeking proposals to close independently identified gaps for clinicians including: Nephrologists, Cardiologists, Endocrinologists, Family and Primary Care MD’s, Nurses, NP/PA’s, Dieticians and Dialysis professionals treating patients with chronic kidney disease. **Proposals can target one or multiple audiences.** Proposals should address one or more of the following gaps.

1. Develop plans for integrating new data on the optimal management of patients with CKD-MBD published since the KDIGO guidelines
2. Address problems with adherence through recognition of patient challenges and implementation of strategies to improve adherence
3. Recognize the implications of calcium levels in CKD and the potential role of calcium vs non-calcium phosphate binders
4. Individualize phosphorus therapy and management
5. Review the relationship between CKD-MBD and CVD to improve treatment and develop strategies to improve patient management and outcomes.

Please note that proposals are expected to include the perspectives of patients in the analysis of the barriers and root causes for this gap and appropriately designed educational interventions.

Proposal should include the following information:

- **Needs Assessment/Gaps/Barriers:** Include a comprehensive needs assessment that is well referenced and demonstrates an understanding of the specific gaps and barriers of the target audiences (i.e., ACCME accreditation element 2). The needs assessment must be independently developed and validated by the accredited provider.

- **Target Audience and Audience Generation:** Proposal should describe the target audience(s) and provide a rational for how and why this target audience is important to closing the identified healthcare gap. In addition, please describe methods for reaching the target audience(s) including description of and rationale for recruitment and placement strategies to maximize participation according to need. Any unique recruitment efforts specific to the target audience should be highlighted.

- **Learning Objectives and Content Accuracy:** Provide clearly defined and measurable learning objectives framed as expected practice improvements in relation to the identified gaps and barriers. Include an overview of program content and explanation of criteria that will guide content selection, considering level of evidence and other variables. Sanofi-aventis is committed to the highest standards in ensuring patient safety; the applicant should describe methods to ensure complete, accurate, evidence-based review of key safety data for any therapeutic entities discussed in the activity. Explain how content will be updated if necessary throughout the program period, and how accuracy will be ensured.

- **Educational Methods:** The ACCME calls for educational methods that are clearly designed to address the knowledge, competence and/or performance gaps that may underlie an identified healthcare gap. Your proposal should demonstrate an understanding instructional design issues as they relate to the gaps in the knowledge, competence, or performance of the targeted audience. Education methods and design should be based on current literature in CME best practice and consistent with ACCME accreditation elements 3,4,5,6. For example, systematic reviews have suggested that the most effective continuing education is clearly linked to clinical practice, uses methods including interaction, reflection, strategies that ensure reinforcement through use of multiple educational interventions, and more. Preference will be given to applications that utilize methods that have been shown to result in practice improvements, and/or with data on the effectiveness of other programs of the same type. ACCME criteria recognize that barriers may be related to systems, lack of resources, or tools etc. and these may be included if relevant in your discussion of the gap and the educational methods you propose. In addition, the educational preferences of the target audience(s) may be considered to maximize attendance/participation and lead to practice improvements.
• **Faculty Recruitment and Development**: Provide information on the expected qualifications of contributors and description of methods to ensure recruitment of course directors and faculty who meet the qualifications. Explain any methods that will be used to ensure that faculty are fully trained in the program expectations and any skills that may be needed to ensure effective delivery of intended education.

• **Program Evaluation and Outcomes**: Provide a description of the approach to evaluate the reach and quality of program delivery; methods for monitoring individual activities and for ensuring ongoing quality improvements (Accreditation elements 12, 13, 14, 15). Describe methods that will be used to determine the extent to which the activity has served to close the identified healthcare gap. (Accreditation Elements 10, 11, 12), and the qualifications of those involved in the design and analysis of the outcomes. Preference will be given to programs with Objectives and Outcomes Plans of Moore level 4-6.14

• **Budget**: Include a detailed budget with rationale including breakdown of costs, clear explanation of the units, and calculations of:
  - Content cost per activity
  - Out-of-pocket cost per activity
  - Management cost per activity

  *Single supported and multi-supported proposals will be considered, with a maximum request from Sanofi not to exceed $200,000.*

• **Accreditation**: Programs must be accredited by the appropriate accrediting bodies and fully compliant with all ACCME criteria and Standards for Commercial Support. If you are a non-accredited provider, the accredited provider must be involved from the concept origin, fully knowledgeable of the grant submission and documentation should be provided on the website grant application section entitled, “Other Information”.

• **Resolution of Conflict**: The proposal should briefly describe methods for ensuring fair and balanced content, identification and resolution of conflict of interest, with particular emphasis on ACCME criteria 7, 8, 9.

• **Communication and Publication Plan**: Provide a description of how the provider will keep the supporter informed of progress. Include description of how the results of this educational intervention will be presented, published or disseminated.
References in RFP

1. JAMA 2007 Nov 7;298(17):2038-47


3. Centers for Disease Control and Prevention

4. Chronic Kidney Disease Mineral and Bone Disorder NIH Publication No. 09–4630
   February 2009
   http://www.niddk.nih.gov/health-information/health-topics/kidney-disease/chronic-

5. Ten-year experience with sevelamer and calcium salts as phosphate binders.
   Raggi P, Vukicevic S, Moysés RM, Wesseling K, Spiegel DM.
   Review.

6. David J.A. Goldsmith , Adrian Covic , Denis Fouque , Francesco Locatelli, Klaus Olgaard,
   Mariano Rodriguez, Goce Spasovski, Pablo Urena, Carmine Zoccali, Gérard Michel
   London and Raymond Vanholder. Endorsement of the Kidney Disease Improving Global
   Outcomes (KDIGO) Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD)
   Guidelines: a European Renal Best Practice (ERBP) commentary statement. Nephrol

Additional References

   Atlanta. Atlanta, GA: Centers for Disease Control and Prevention, US Dept of Health and Human

guideline for the evaluation and management of chronic kidney disease. Kidney Inter.

   incident myocardial infarction and all-cause and cardiovascular disease mortality in middle-aged

   and End-Stage Renal Disease in the United States. Bethesda, MD: National Institutes of Health,

5. US Renal Data System. USRDS Renal Data Extraction and Referencing (RenDER) System.

6. Astor BC, Hallan SI, Miller ER 3rd, Yeung E, Coresh J. Glomerular filtration rate, albuminuria,


8. Go AS, Chertow GM, Fan D, McCulloch CE, Hsu CY. Chronic kidney disease and the risks of