

A world map in shades of blue and white, overlaid with various medical icons such as a syringe, a pill, a location pin with a cross, a microscope, and a person in a wheelchair. The icons are arranged in a grid-like pattern over the map.

# **Pfizer and the National Kidney Foundation Announce**

## ***Improving Immunization Rates of Patients with Chronic Kidney Disease Including Dialysis Patients***

### **Competitive Grant Program – using External Review Panel**

## **I. Background**

Pfizer and the National Kidney Foundation are collaborating to offer a new grant opportunity focused on supporting quality improvement (QI) initiatives that will result in an increase in immunization rates of adults with immunocompromising conditions, specifically patients with Chronic Kidney Disease (CKD) including dialysis patients, in accordance with Advisory Committee on Immunization (ACIP) recommendations.

The mission of Pfizer Global Medical Grants (GMG) is to support the global healthcare community's independent initiatives (e.g., research, quality improvement or education) to improve patient outcomes in areas of unmet medical need that are aligned with Pfizer's medical and/or scientific strategies.

The mission of the National Kidney Foundation, a major voluntary nonprofit health organization, is to prevent kidney and urinary tract diseases, improve the health and well-being of individuals and families affected by kidney disease and increase the availability of all organs for transplantation.

Pfizer's GMG competitive grant program involves a publicly posted Request for Proposal (RFP) that provides detail regarding a specific area of interest, sets timelines for review and approval, and uses an external review panel (ERP) to make final grant decisions. Organizations are invited to submit an application addressing the specific gaps in practice as outlined in the specific RFP.

For all quality improvement grants, the grant requester (and ultimately the grantee) is responsible for the design, implementation, and conduct of the independent initiative supported by the grant. Pfizer must not be involved in any aspect of project development, nor the conduct or monitoring of the quality improvement program.

## II. Eligibility

<b>Geographic Scope</b>	United States
<b>Applicant Eligibility Criteria</b>	<ul style="list-style-type: none"> <li>• The following may apply: medical, nursing, allied health, and/or pharmacy professional schools; healthcare institutions (both large and small); professional associations; government agencies; and other entities with a mission related to healthcare improvement.</li> <li>• Collaborations within institutions (e.g., between departments and/or inter-professional), as well as between different institutions / organizations / associations, are encouraged. Please note all partners must have a relevant role and the requesting organization must have a key role in the project.</li> <li>• For programs offering credit, the requesting organization must be the accredited grantee.</li> </ul>

## III. Requirements

<b>Date RFP Issued</b>	<ul style="list-style-type: none"> <li>• April 9, 2019</li> </ul>
<b>Clinical Area</b>	<ul style="list-style-type: none"> <li>• Vaccine Preventable Diseases</li> </ul>
<b>Specific Area of Interest for this RFP:</b>	<p>It is our intent to support quality improvement projects that focus on increasing the percentage of adults with immunocompromising conditions, specifically patients with Chronic Kidney Disease (CKD) including dialysis patients, who are immunized against vaccine preventable diseases.</p> <p>During review, the intended outcome of the project is given careful consideration and, if appropriate based on the project goal, projects with the maximum likelihood to directly impact patient care will be given high priority. (Projects including an educational element can find more information on principals of learning and behavior change for health professionals at <a href="http://www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf">www.pfizer.com/files/HealthProfessionalsLearningandBehaviorChange_AFewPrinciples.pdf</a>.)</p> <p><i>The efficacy of therapeutic or diagnostic agents will not be considered. Information on how to submit requests for support of clinical research projects can be found at <a href="http://www.Pfizer.com/isr">www.Pfizer.com/isr</a>.</i></p>

<b>Target Audience:</b>	<ul style="list-style-type: none"><li>Healthcare clinicians and their practice team working to immunize dialysis patients and patients with Chronic Kidney Disease (CKD)</li></ul>
<b>Disease Burden Overview:</b>	<ul style="list-style-type: none"><li>Infections after cardiovascular disease are the second most common cause of death in the chronic kidney disease population. Vaccination is an important component of maintaining health and wellness in patients with kidney disease.<sup>1</sup></li><li>Chronic kidney disease (CKD) is a worldwide public health problem. According to an article in the Journal of the American Medical Association (JAMA), 30 million adults in the United States have CKD.<sup>2</sup> There is an increasing incidence and prevalence of patients with kidney failure requiring renal replacement therapy (dialysis) with poor outcomes and high cost. The 2010 prevalent population for patients with end-stage renal disease (ESRD) on hemodialysis, peritoneal dialysis, or with a functioning kidney transplant was 593,086 – which was a growth of 4% from 2009.<sup>3</sup></li></ul> <p>Kidney disease and kidney failure interferes with the body’s natural immunity, making it easier to acquire infectious diseases. For instance, compared with the non-CKD population, the rates of pneumonia are 3 times greater in the CKD population and 5 times greater in the dialysis population.</p> <p>The average age of the patient undergoing dialysis in the United States has been steadily increasing over the last several decades. In 2000, the average age was approximately 62 years.<sup>4</sup> However, overall, patients on dialysis have a naturally weaker immune system resulting from their dialysis treatment. Additionally, co-morbid conditions can predispose them to preventable infections.</p> <p>Bacteremia/sepsis patterns are also quite different when comparing the non-CKD, CKD, and dialysis populations, with infection rates 4 times greater in the CKD population and almost 10 times greater in the dialysis population than in the non-CKD population.<sup>5</sup></p> <p>Hemo- and peritoneal dialysis patients may be exposed to infection by contact with other patients, contamination of facility surfaces with blood, stool or body fluids, and by catheters traversing the body’s natural protective barriers. The majority of these patients require at least 1 hospitalization every year for treatment of infections.<sup>6</sup></p> <p>Consequently, there is a clear need for healthcare practitioners, patients, and caregivers to be educated on infectious disease risks and methods to decrease these risks.</p>

<p><b>Recommendations and Target Metrics:</b></p>	<p><b>Related Guidelines and Recommendations</b></p> <ul style="list-style-type: none"> <li>• Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older — United States, 2019<sup>7</sup></li> <li>• National Vaccine Advisory Committee’s Standards for Adult Immunization Practices<sup>8</sup></li> <li>• US Department of Health and Human Services. Healthy People 2020 objective IID-1: Reduce, eliminate, or maintain elimination of cases of vaccine-preventable diseases.<sup>9</sup></li> </ul>
<p><b>Gaps Between Actual and Target, Possible Reasons for Gaps:</b></p>	<ul style="list-style-type: none"> <li>• Vaccination coverage levels among U.S. adults are not optimal.<sup>10</sup></li> <li>• For example, reported influenza vaccination coverage among high-risk persons aged 18-64 was 45.4%<sup>11</sup>, falling short of the Healthy People 2020 goal of 90%<sup>12</sup> and reported pneumococcal vaccination coverage among adults aged 19–64 years at increased risk for pneumococcal disease was 23.0%<sup>13</sup>, falling short of the Healthy People 2020 goal of 60%<sup>12</sup></li> <li>• Reasons for under-vaccination of special groups include fear of adverse outcomes or illness caused by the vaccine, the inconvenience (and in some settings, cost) of vaccination and lack of awareness of the need for vaccination or national recommendations<sup>14</sup></li> </ul>
<p><b>Barriers:</b></p>	<ul style="list-style-type: none"> <li>• There is no clear explanation for the low vaccination rates among patients with CKD, in particular patients on dialysis.<sup>1</sup></li> <li>• Cost of providing vaccination services<sup>15</sup></li> <li>• Inadequate or inconsistent payment for vaccines/vaccine administration<sup>15</sup></li> <li>• Specialists caring for patients with CKD may overlook vaccination because of lack of adequate knowledge on immunizations deferring it to the general practitioner, who in turn may not want to interfere in CKD care and regard vaccination as a specialist’s responsibility.<sup>16</sup></li> <li>• Acute medical care taking precedence over preventive services<sup>15</sup></li> </ul>
<p><b>Current National Efforts to Reduce Gaps:</b></p>	<p>Many efforts have been made to promote vaccination. Below are some examples of efforts made by various organizations.</p> <ul style="list-style-type: none"> <li>• Resources from the National Kidney Foundation: <a href="https://www.kidney.org/atoz/content/what_infectdiseases">https://www.kidney.org/atoz/content/what_infectdiseases</a></li> <li>• The National Vaccine Advisory Committee (NVAC) has posted tools and resources to help healthcare professionals implement the Standards for Adult Immunization Practice (<a href="https://www.cdc.gov/vaccines/hcp/adults/for-practice/standards/index.html">https://www.cdc.gov/vaccines/hcp/adults/for-practice/standards/index.html</a>)</li> <li>• Substantial resources from the CDC, ranging from extensive reports on ACIP recommendations and practical Vaccine Information Statements, patient-focused materials on frequently asked questions, and more (<a href="https://www.cdc.gov/vaccines/index.html">https://www.cdc.gov/vaccines/index.html</a>)</li> </ul>

	<ul style="list-style-type: none"> <li>• CDC Adult Immunization Schedule (<a href="http://www.cdc.gov/vaccines/schedules/index.html">http://www.cdc.gov/vaccines/schedules/index.html</a>)</li> <li>• HealthyPeople.gov <a href="https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives">https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives</a></li> </ul>
<p><b>Expected Approximate Monetary Range of Grant Applications:</b></p>	<ul style="list-style-type: none"> <li>• Individual projects requesting up to \$75,000 will be considered. The total available budget related to this RFP is \$225,000.</li> </ul>
<p><b>Key Dates:</b></p>	<ul style="list-style-type: none"> <li>• RFP release date: April 9, 2019</li> <li>• LOI due date: May 15, 2019 Please note the deadline is midnight Eastern Time (New York, GMT -5).</li> <li>• Anticipated LOI Notification Date: week of June 3<sup>rd</sup></li> <li>• Full Proposal Deadline: *July 15, 2019 *Only accepted LOIs will be invited to submit full proposals Please note the deadline is midnight Eastern Time (New York, GMT -5).</li> <li>• Anticipated Full Proposal Notification Date: week of August 12<sup>th</sup></li> <li>• Grants distributed following execution of fully signed Letter of Agreement</li> <li>• Anticipated Project Start Dates: October 2019</li> </ul>
<p><b>How to Submit:</b></p>	<ul style="list-style-type: none"> <li>• Please go to <a href="http://www.cybergrants.com/pfizer/loi">www.cybergrants.com/pfizer/loi</a> and sign in to submit your Letter of Intent. First-time users should click “Create your password”.</li> <li>• Requirements for submission:             <ul style="list-style-type: none"> <li>• Select the following Competitive Grant Program Name: Improving Immunization of Dialysis Patients and Patients with CKD</li> <li>• Select the following Primary Area of Interest: Vaccine Preventable Disease - Public Health and General Vaccinology</li> <li>• Complete all required sections of the online application and upload the completed LOI template (see Appendix).</li> </ul> </li> <li>• If you encounter any technical difficulties with the website, please click the “Technical Questions” link at the bottom of the page.</li> </ul> <p><b>IMPORTANT:</b> Be advised applications submitted through the wrong application type and/or submitted after the due date will not be reviewed by the committee.</p>
<p><b>Questions:</b></p>	<ul style="list-style-type: none"> <li>• If you have questions regarding this RFP, please direct them in writing to Jessica Joseph (<a href="mailto:JessicaJ@kidney.org">JessicaJ@kidney.org</a>) and Amanda Stein (<a href="mailto:amanda.j.stein@pfizer.com">amanda.j.stein@pfizer.com</a>), with the subject line “Improving Immunization of Dialysis Patients and Patients with CKD”.</li> </ul>





<b>Review and Approval Process</b>	<ul style="list-style-type: none"> <li>A specific grant program RFP uses an external review panel (ERP) to make final grant decisions.</li> <li>The panels are comprised of professionals from the medical community with advanced degrees and expertise in particular clinical areas, or specific needs of a geographic region/learner group, or expertise in research, continuing professional development or quality improvement.</li> </ul>
<b>Mechanism by which Applicants will be Notified:</b>	<ul style="list-style-type: none"> <li>All applicants will be notified via email by the dates noted above.</li> <li>Applicants may be asked for additional clarification during the review period.</li> </ul>

## References:

1. Snigdha Reddy, Chandrika Chitturi, Jerry Yee, Vaccination in Chronic Kidney Disease, *Advances in Chronic Kidney Disease*, Volume 26, Issue 1, 2019, Pages 72-78, ISSN 1548-5595, <https://doi.org/10.1053/j.ackd.2018.10.002>.
2. United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.
3. U.S. Renal Data System: USRDS 2012 Annual Data Report. Atlas of End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2012.
4. Hansberry MR, Whittier WL, Krause MW. The elderly patient with chronic kidney disease. *Adv Chronic Kidney Dis* 2005; 12:71.
5. Sakina B., Collins A. "Infectious Complications in Chronic Kidney Disease." *Adv in CKD*, Vol 13, No 3 (July), 2006: pp 199-204
6. U.S. Renal Data System: USRDS 1997 Annual Data Report. Bethesda, Maryland, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 1997
7. Kim, DK Hunter P. Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older — United States, 2019. *MMWR Morb Mortal Wkly Rep* 2019;68:115–118. DOI: <http://dx.doi.org/10.15585/mmwr.mm6805a5>
8. National Vaccine Advisory Committee. Recommendations from the National Vaccine Advisory Committee: Standards for Adult Immunization Practice. *Public Health Reports*. 2014; Volume 129 (115-123)
9. US Department of Health and Human Services. Healthy People 2020 objectives. Available at:

<http://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives>. Accessed January 4, 2019.

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11. O'Halloran AC, Lu PJ, Williams WW, Bridges CB, Singleton JA. Influenza vaccination coverage among people with high-risk conditions in the U.S. *Am J Prev Med* 2016;50:e15-e26.
12. Williams WW, Lu P, O'Halloran A, et al. Surveillance of Vaccination Coverage among Adult Populations — United States, 2015. *MMWR Surveill Summ* 2017;66(No. SS-11):1–28. DOI: <http://dx.doi.org/10.15585/mmwr.ss6611a1> Wick JY. Pharmacy Times. Roll up your sleeves: adult immunizations. Available at: [www.pharmacytimes.com/publications/issue/2013/march2013/roll-up-your-sleeves-adult-immunizations](http://www.pharmacytimes.com/publications/issue/2013/march2013/roll-up-your-sleeves-adult-immunizations). Accessed April 1, 2019
13. Centers for Disease Control and Prevention. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine for adults with immunocompromising conditions: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep*. 2012;61(40):816-819.
14. Vaccination of special populations: protecting the vulnerable. *Vaccine*, 34 (2016), pp. 6681-6690 M. Doherty, et al.
15. Bridges CB, Hurley LP, Williams WW, Ramakrishnan A, Dean AK, Groom AV. Meeting the challenges of immunizing adults. *Am J Prev Med* 2015;49(Suppl 4):S455–64
16. Rubin LG, Levin MJ, Ljungman P, et al. 2013 IDSA clinical practice guideline for vaccination of the immunocompromised host *Clin Infect Dis*. 2014;58(3):309-318.

#### IV. Terms and Conditions

Please take note every Request for Proposal (RFP) released by Pfizer Global Medical Grants, as well as a RFP released jointly with a Partner(s), is governed by specific terms and conditions. Click [here](#) to review these terms and conditions.

## Appendix A

### Letter of Intent Requirements

The Letter of Intent (LOI) will be accepted via the online application. When answering the LOI questions in the application please keep the following in mind:

<p><b>Goals and Objectives</b></p>	<ul style="list-style-type: none"> <li>• Briefly state the overall goal of the project. Also describe how this goal aligns with the focus of the RFP and the goals of the applicant organization(s).</li> <li>• List the <i>overall</i> objectives you plan to meet with your project both in terms of learning and expected outcomes. Objectives should describe the target population as well as the outcomes you expect to achieve as a result of conducting the project.</li> </ul>
<p><b>Assessment of Need for the Project</b></p>	<ul style="list-style-type: none"> <li>• Please include a quantitative baseline data summary, initial metrics (e.g., quality measures), or a project starting point (please cite data on gap analyses or relevant patient-level data that informs the stated objectives) in <i>your</i> target area. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. If a full analysis has not yet been conducted, please include a description of your plan to obtain this information. The RFP includes a national assessment of the need for the project. Please do not repeat this information within the LOI (you may reference the RFP, if necessary). Only include information that impacts your specific project, linking regional or local needs to those identified on the national basis, if appropriate.</li> </ul>
<p><b>Target Audience</b></p>	<ul style="list-style-type: none"> <li>• Describe the primary audience(s) targeted for this project. Also indicate whom you believe will directly benefit from the project outcomes. Describe the overall population size as well as the size of your sample population</li> </ul>
<p><b>Project Design and Methods</b></p>	<ul style="list-style-type: none"> <li>• Describe the planned project and the way it addresses the established need.</li> <li>• If your methods include educational activities, please describe succinctly the topic(s) and format of those activities</li> </ul>
<p><b>Innovation</b></p>	<ul style="list-style-type: none"> <li>• Explain what measures you have taken to assure that this project idea is original and does not duplicate other projects or materials already developed.</li> <li>• Describe how this project builds upon existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.</li> </ul>



<p><b>Evaluation and Outcomes</b></p>	<ul style="list-style-type: none"> <li>• In terms of the metrics used for the needs assessment, describe how you will determine if the practice gap was addressed for the target group. Describe how you expect to collect and analyze the data.</li> <li>• Quantify the amount of change expected from this project in terms of your target audience.</li> <li>• Describe how the project outcomes will be broadly disseminated.</li> </ul>
<p><b>Anticipated Project Timeline</b></p>	<ul style="list-style-type: none"> <li>• Provide an anticipated timeline for your project including project start/end dates</li> </ul>
<p><b>Additional Information</b></p>	<ul style="list-style-type: none"> <li>• If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please summarize here</li> </ul>
<p><b>Organization Detail</b></p>	<ul style="list-style-type: none"> <li>• Describe the attributes of the institutions / organizations / associations that will support and facilitate the execution of the project and the leadership of the proposed project. Articulate the specific role of each partner in the proposed project. Letters of support from partner organizations will be required at the Full Proposal stage only and should not be included with the LOI.</li> </ul>
<p><b>Budget Detail</b></p>	<ul style="list-style-type: none"> <li>• A total amount requested is the only information needed for the LOI stage. Full Budget is not required. This amount can be adjusted at the Full Proposal stage as applicable.</li> <li>• The budget amount requested must be in U.S. dollars (USD).</li> <li>• While estimating your budget please keep the following items in mind:             <ul style="list-style-type: none"> <li>○ Institutional overhead and indirect costs may be included within the grant request. Examples include human resources department costs, payroll processing and accounting costs, janitorial services, utilities, property taxes, property and liability insurance, and building maintenance as well as additional project expenses such as costs for publication, IRB / IEC review fees, software license fees, and travel. Please note: Pfizer does not provide funding for capital equipment.</li> <li>○ The inclusion of these costs cannot cause the amount requested to exceed the budget limit set forth in the RFP.</li> <li>○ It should be noted that grants awarded through GMG cannot be used to purchase therapeutic agents (prescription or non-prescription).</li> </ul> </li> <li>• Pfizer maintains a company-wide, maximum allowed overhead rate of 28% for independent studies and projects</li> </ul>