Prescription drug use, health outcomes, and non-drug medical spending in the elderly – Evaluation of changes in prescription drug benefits in Medicare

Kyoungrae Jung (Principal Investigator), Douglas Leslie, A. Marshall McBean

1. Keywords: Prescription drug benefits, health outcomes, non-drug medical spending, the elderly, Medicare Part D

2. Abstract
Prescription drugs are cost-effective treatments for many health conditions, particularly for chronic illnesses. Pharmacy coverage is thus an essential benefit of health insurance policies, and developing programs to increase access to prescription drugs and thereby improve population health has been an ongoing policy goal. The introduction of Medicare Part D (Medicare drug benefits) in 2006 was a significant move toward this goal for the elderly and disabled populations who often have multiple chronic conditions. The recent health care reform legislation – the 2010 Affordable Care Act (ACA) – has further expanded prescription drug coverage for Medicare beneficiaries by reducing cost sharing in a benefit phase in the standard Part D benefit scheme. As pharmacy therapy plays an increasingly important role in treating health problems, it is expected that the expansions of prescription drug coverage for Medicare beneficiaries would potentially improve health outcomes of beneficiaries and thus save costs of nondrug medical services, such as hospitalizations or skilled nursing facility use. However, evidence on the relationship between drug benefit generosity and health outcomes is limited particularly among high-risk Medicare beneficiaries with certain chronic conditions or high-cost drug users. We propose to conduct exploratory analysis on the impacts of enhanced prescription drug benefits on the use and spending on nondrug medical services and health outcomes, which will be used for the preliminary analysis section in a grant application for external funding.

3. Specific Aims and Objectives
The objective of this proposal is to conduct exploratory analysis on prescription drug use and health outcomes among the elderly Medicare beneficiaries with chronic conditions and to develop a grant application to the Changes in Health Care Financing and Organization (HCFO) program by Robert Wood Johnson Foundation (RWJF). This application would evaluate changes in Medicare prescription drug benefits (Medicare Part D), addressing a series of research questions on the relations between prescription drug benefits, non-drug medical spending, and health outcomes in the elderly. A purpose of this proposal is also to facilitate collaboration between researchers at Penn State (both from the Department of Health Policy and Administration at University Park campus and the College of Medicine in Hershey) and a researcher at the University of Minnesota for the development of a grant application for external funding. Specifically, we will

1) Extract 12 years of Medicare Current Beneficiary Survey (MCBS) data (2000 – 2012) to construct analytic data files
2) Analyze patterns of overall prescription drug use and brand-name drug utilization during the study period
3) Explore changes in inpatient and outpatient service use and expenditures, as well as health
status and functional outcomes during the study period

4) Check whether subgroup analyses by chronic condition group would be feasible
   a) Obtain the number of beneficiaries with a chronic illness whose drug cost is high, including cardiovascular diseases, depression, dementia, osteoporosis, and cancer etc.
   b) Examine drug utilization and health outcomes in each condition group

5) Conduct a literature review on prescription drug use and health outcomes in the elderly

6) Develop an application for external funding for an evaluation of Part D with particular attention to the impact of filling in the coverage gap— which is mandated by ACA.

4. Background, Rationale, and Methods
Medicare Part D, which was introduced in 2006, provides prescription drug coverage to 25.5 million elderly and disabled people. The program has been successful in increasing overall drug utilization while decreasing beneficiaries’ out-of-pocket spending.\(^1\) However, evidence on whether and how the improvement in drug benefits influences the use of other medical services among Medicare beneficiaries is sparse. Several prior studies examined this issue using data from the initial years of Part D (2006 and 2007).\(^2\) However, these studies are limited to examining a few outcome measures (mostly hospitalization rates/costs) for a small group of beneficiaries from one managed care organization or a survey, whose results may not be generalizable to a large portion of beneficiaries or other outcomes. Further, evaluating the early years of Part D, those studies may have captured pent-up demand for prescription drugs among those without drug coverage prior to Part D. No information is available on long-term effects of Part D on health outcomes. Moreover, little is known about the impacts of drug benefits on drug use and health outcomes for high-risk Medicare beneficiaries or high-cost drug users, whose drug spending accounts for a large share of Medicare spending and is a key policy issue in Medicare Part D.\(^3\)

These issues highlight the need for studies on the relation between drug benefit generosity and health outcomes. As pharmacy therapy plays an increasingly important role in treating health problems, drug benefit designs that ensure access to cost-effective drugs, particularly among high-risk consumers, have become critical elements of efficient health care systems. By evaluating the Part D program, our study will provide information that can be used to design such benefits.

Medicare Part D benefits:
While the Part D program is generally considered successful, the presence of a coverage gap in the standard Part D benefit has been criticized as a limitation of the program. Under the standard Part D benefit, after reaching an Initial Coverage Limit (ICL; total drug spending of $2,830 in 2010) beneficiaries enter the coverage gap, where they become responsible for the full cost of drugs. Studies reporting a decrease or discontinuation of prescription drug use in the gap raised concerns about its adverse effect on beneficiaries’ health, particularly for high-risk beneficiaries with chronic conditions. In response, the ACA stipulates that the gap will be gradually filled in until it is fully closed by 2020. This ACA provision began in 2011 with 50% discounts on branded

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\(^1\)Polinski et al. (2010). Changes in drug utilization and out-of-pocket costs associated with Medicare Part D implementation: A systematic review. *Journal of American Geriatric Society*, 58(9), 1764-1779


\(^3\)Medicare Payment Advisory Committee. (MedPAC, 2012; 2013). Reports to Congress: Medicare payment policy.
drugs from manufacturers and 7% discounts on generic drugs from the government. The government subsidy will increase gradually until beneficiaries are responsible for 25% of the cost for both generic and branded drugs in 2020. This is a significant change in Part D, which will further increase beneficiaries’ prescription drug use and can potentially improve their health outcomes. While filling in the gap will add costs to Part D, it may reduce spending on medical care (e.g., hospitalizations). Our study will evaluate the changes in Medicare drug benefits – both the introduction of Part D and the recent ACA expansion. Particularly, the ACA expansion offers a unique opportunity to address several issues related to drug benefits, drug use and health outcomes. First, serving as a natural experiment, it enables us to examine a causal effect of enhanced drug benefits on health outcomes. Further, under the ACA provision, discounts in the coverage gap are much more favorable for brand-name drugs than generic drugs. This allows us to focus on high-risk beneficiaries with chronic conditions, who often rely on costly brand name drugs that do not have substitutes.

Medicare Current Beneficiary Survey (MCBS) data (2000-2012):
The MCBS is a continuous survey of a nationally representative sample of the Medicare population, which is conducted by the Center for Medicare and Medicaid Services (CMS). In any year, more than 15,000 beneficiaries are interviewed. Each sample person is interviewed three times a year over four years, and the sample is replenished with approximately twenty-five percent new subjects each year. We will use two modules of MCBS data – Access to Care and Cost and Use files – which will be purchased from CMS. The Access to Care file contains information on demographic and economic characteristics of the sample population, as well as self-reported health status and functional outcomes (e.g., independency in activities in daily lives). The Cost and Use file is a source of data on all health care services, including hospitalizations, physician office visits, and prescription drug use. With these two files, we will explore how generous drug benefits influence prescription drug use and health outcomes in the elderly. Further, using sampling weights provided in MCBS data, we will calculate sample sizes for analyses that would be proposed in a grant application for external funding and assess feasibility and power of those analyses.

Descriptive analysis:
Using 12 years of MCBS data, we will first examine patterns of prescription drug use in the elderly over years – both overall utilization and by chronic condition. This descriptive analysis will help assess whether the changes in prescription drug utilization after 2006 (implementation of Part D) and after 2011 (reduced cost sharing in the coverage gap) are large enough to indicate that the enhanced drug benefit affects beneficiaries’ use of prescription drugs. Our primary focus is on examining whether prescription drug use continuously increased during the later years of Part D (the long-term effect of Part D) and whether a greater increase in prescription drug use occurred after 2011 (the impact of the ACA expansion). It will also help identify subgroups – by chronic condition – that are worth investigating. We will examine similar descriptive time trends in diverse measures of health outcomes and non-drug medical service use, including self-reported health status, functional outcomes, hospital admissions, length of stay per admission, hospital admissions through emergency room, and acute-care sensitive hospitalizations, and physician office visits etc. This descriptive analysis will inform us of potential impacts of the enhanced drug benefit on health outcomes and nondrug medical spending.
Exploring control-group strategies:
Next, we will explore control-group strategies for the RWJF application because the analysis above may simply capture time trends in outcome measures rather than the impacts of the drug benefit change. An appropriate control group would be beneficiaries who are not affected by the change in Medicare drug benefits. To examine long-term effects of the implementation of Part D, we will explore, as a possible control group, beneficiaries who did not have drug coverage prior to 2006. To evaluate filling in the coverage gap in Part D (the ACA expansion), we will identify beneficiaries who received low-income subsidies (LIS) and thus did not face the coverage gap before 2011 (but after the implementation of Part D). We will first look at descriptive data, i.e., over-time changes in prescription drug use, medical service use/spending, and health outcomes in those possible control groups. We will then explore a difference-in-difference approach, which assesses whether changes in outcome measures in an experiment group are different than those in a control group. This will help us gauge the magnitude of the effects of the drug benefit change after controlling for a secular trend. Finally, we will explore the validity of those possible control groups by comparing patterns of prescription drug use prior to any policy changes between the experiment and control groups. In other words, if the time trends in prescription drug use before any policy changes are different between the two groups, it would suggest that proposed control groups might not be appropriate comparisons. If this would be the case, we would identify beneficiaries who are relatively similar to the control groups (in demographic characteristics and health conditions) and limit our analysis to these “relatively similar” groups.

Developing a grant application for external funding:
The preliminary analyses described above will provide information that will be used for the development of an application for external funding. The application would propose to use multiple years of a set of Medicare claims files, which provides comprehensive information on the use and spending on inpatient, skilled nursing facility, outpatient care, and prescription drugs, and mortality, for millions of beneficiaries. Using these large claims data will improve power of analyses and generalizability of study findings. The application would ask:

1) What are the long-term effects of the implantation of Part D in the elderly beneficiaries?
   a) Does the implementation of Part D increase prescription drug use in a long term?
   b) Does the implementation of Part D improve health outcomes of the elderly and save costs of other medical services in a long run?

2) How do the long-term effects of the introduction of Part D on the use prescription drugs and health outcomes vary by beneficiaries’ health-risk or chronic condition(s)?

3) Does the reduced cost sharing in the coverage gap in Part D increase prescription drug use?
   a) Does reduced cost sharing in the coverage gap in Part D lead beneficiaries with chronic condition(s) to initiate a pharmacy therapy?
   b) Does reduced cost sharing in the coverage gap in Part D improve medication compliance?
   c) Are beneficiaries less likely to discontinue medications in the gap after 2011 than prior years?
   d) Does reduced cost sharing in the coverage gap in Part D increase the use of brand name drugs under the ACA provision that gives favorable discounts for branded drugs?

4) Does reduced cost sharing in the coverage gap in Part D influence the use and spending on
nondrug medical services (e.g., in-patient admissions, skilled nursing facility admissions and physician office visits) and health outcomes (e.g., reduced mortality)?

5) Do beneficiaries’ responses to filling in the coverage gap by ACA in the use prescription drugs and other medical services vary by their health-risk or chronic conditions?

This proposed study would also begin a research partnership among researchers with diverse skills, experience and expertise. Along with the collaboration on the proposed exploratory analysis, the research team would discuss the following issues to develop an application for external funding.

1) Selection of chronic conditions to focus on: we would select several chronic conditions that are clinically and economically important. Selection criteria would include: a) the number of beneficiaries with the condition (sample size); b) total health care costs of the condition; and c) whether health outcomes of patients with the condition are sensitive to prescription drug use (e.g., non-adherence to osteoporosis drugs often leads to fractures).

2) Refining research design: the application would propose to utilize longitudinal data, which allow us to use an interrupted time-series design and/or a difference-in-difference approach, both of which are commonly-used methods to evaluate policy changes. We will further refine research methods and control-group strategies based on findings from this proposed study.

3) Construction of outcome measures: we would discuss what outcome measures (both health outcome and prescription drug utilization measures) to use in the application and how to construct them. We will explore several health outcome measures in this proposed study and select measures that produce informative results (e.g., overall hospital admissions vs. acute care sensitive hospitalizations vs. hospital admissions through emergency room).

5. Relevance to the SSRI:
This research fits in the SSRI mission to promote research involving broad range of skills and perspectives that are necessary to address social policy issues. The research team of this project consists of researchers with diverse expertise and experience. As described below, this project involves a medical doctor and epidemiologist from the University of Minnesota, a senior economist from the Penn State College of Medicine, and a health policy researcher in the Department of Health Policy and Administration (HPA) at Penn State. Health services research is essentially built with an interdisciplinary approach, and our research team offers disciplines as diverse as economics, epidemiology/public health, and health policy. Bringing together investigators with diverse skills, experience and expertise, this project aims to address important health care policy issues.

6. Anticipated Outcomes:
The product of this effort will be an application submitted to RWJF in spring 2014. If the application is not well received by RWJF, we will submit an R01 application to the National Institute of Aging (NIA) in June 2014. We will also consider the National Institute of Mental Health (NIMH) or National Heart, Lung, and Blood Institute (NHLBI) or National Cancer Institute (NCI), depending on findings from exploratory analyses. Over the long term, this project would result in increased collaborations between the UP campus and the College of Medicine.
Additional Information

1. External Funding Sources
a) Investigators Involved: see below (the same personnel for the proposed study and possibly a few additional members)
b) Title of Proposal: Prescription drug use, health outcomes, and non-drug medical spending in the elderly – Evaluation of changes in prescription drug benefits in Medicare
c) Time Frame of Proposal: the RWJF application will be submitted in spring 2014
d) External funding sources: the primary target agency at this stage is RWJF, but we will also consider NIA, NIMH, NHLBI or NCI, depending on results from exploratory analysis.

2. Timeline:
July/August 2013 – Review literature; obtain MCBS data
Fall 2013 – Construct analytic files; perform data analysis
Spring 2014 – Write up a grant proposal
Spring 2014 – Submission of the application

3. Personnel
The principal investigator, Kyoungrae Jung, is an assistant professor of Health Policy and Administration (HPA). She would supervise the entire process and would develop a research plan and appropriate analytic techniques. She would also assume primary responsibility for writing of the grant application for external funding.

Collaborating investigators:
Dr. Douglas Leslie is a professor of Public Health Sciences and director of Center for Applied Studies in Health Economics at Penn State College of Medicine in Hershey. Dr. Leslie is a health economist whose study areas include adherence to treatment guidelines for mental health patients and the cost-effectiveness of antipsychotic medications. He would provide consultation on research design, and would assist in developing a research plan, particularly in the area of the impact of medication use on health outcomes.

A. Marshall McBean, MD, MSc., is a professor in the Department of Health Policy and Management and director of the Research Data Assistance Center (a CMS contractor) at the University of Minnesota. He has a background in epidemiology and expertise in access, quality of care, and health outcomes of Medicare beneficiaries. Particularly, he has extensive expertise in the data sets required for the application for external funding. He will advise the project on clinical issues, as well as access to data and data management.

Others. During the coming year, we would hope to involve other Penn State faculty members. Possible collaborators include Dennis Shea, a professor of Health Policy and Administration, with expertise in Medicare policies, financing for long-term care, and prescription drug use among the elderly. Another possibility is Frank Ahern, a senior research associate in the Department of Biobehavioral Health, whose research focuses on prescription drug use/misuse among the elderly and long-term care.
4. **Itemized Budget and Justification:**
SSRI seed funds will be used to purchase MCBS data files, fund a graduate student during summer/fall 2013, and partially support Jung’s salary (buy-out of one course) in spring 2014 to help her focus on the grant application for external funding. The graduate student will assist with the necessary literature reviews and data analysis. Funding for Jung to make one trip to Hershey to meet with Dr. Leslie is also requested.

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<th>Description</th>
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<tr>
<td><strong>Salary support for Jung: Spring 2014</strong></td>
<td>$7,500</td>
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<tr>
<td>Research assistant (stipend only): Summer/Fall 2013</td>
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<tr>
<td>- $23.50 X 20 hours/week X 5 weeks (summer 2013) = $2,350</td>
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<tr>
<td>- 10 hours/week (fall 2013) = $4,650 (based on grade 14)</td>
<td>$7,000</td>
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<tr>
<td>Data sets (MCBS files 2009-2012): $600 per module per year</td>
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<tr>
<td>- Two modules/year X 4 years = $4,800</td>
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<tr>
<td>- Other years of data (2000-2008) are in house</td>
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<td>Travel to Hershey</td>
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<td><strong>Total</strong></td>
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Name and phone number of your department's budget coordinator:

Stephen Bumbarger (Tel: 814-863-2860; Email: svb4@psu.edu)

Budget and fund number:

Administrative area number:

5. **SSRI services to be used:** None

6. **Investigator Information**

Lead Investigator:

Name: Kyoungrae Jung  
Title: Assistant Professor  
Address: 601E Ford Building  
City: University Park  
State: PA  
Zip Code: 16802  
Department/Organization: Department of Health Policy and Administration (HPA), The Pennsylvania State University  
College: College of Health and Human Development  
Campus: University Park  
Phone: 814-863-8129  
Fax: 814-863-2905  
Email: kuj11@psu.edu  
Tenure Track - Yes. If Yes, please include tenure home department: HPA
Collaborating Investigator:

Name: Douglas Leslie  
Title: Professor of Public Health Sciences; Director of Center for Applied Studies in Health Economics  
Address: 500 University Drive  
City: Hershey  
State: PA  
Zip Code: 17033  
Department/Organization: Public Health Sciences, The Pennsylvania State University  
College: College of Medicine  
Campus: Hershey  
Phone: 717-531-1259  
Email: dll35@psu.edu  
Tenure Track - Yes. If Yes, please include tenure home department: PHS

Collaborating Investigator:

Name: A. Marshall McBean  
Title: Professor; Director of Research Data Assistance Center (ResDAC)  
Address: 420 Delaware Street SE, MMC 729  
City: Minneapolis  
State: Minnesota  
Zip Code: 55455  
Department/Organization: Health Policy and Management, University of Minnesota  
College: School of Public Health  
Campus: Twin Cities  
Phone: 612-625-6175  
Fax: 612-624-2196  
Email: mcbea002@umn.edu  
Tenure Track - Yes. If Yes, please include tenure home department: HPM

7. Pre-Submission Checklist

1) Which agency or foundation officials (e.g., project officer) have you spoken with to determine their interest in this project or project area? What feedback did you receive on your concept and approach?

HCFO program by RWJF has a formal process to provide feedback on proposal ideas by officially receiving a letter of intent. We will submit the letter in fall 2013. It usually takes about two or three months to receive feedback on the letter. While it would be ideal to apply for seed money and conduct exploratory analysis after we are invited to write a full proposal, researchers are expected to submit a full proposal within only several weeks following invitations. If we wait to hear about the invitation, we will not have sufficient time to write up the full proposal. Therefore, we will start conducting preliminary analysis and preparing for the full proposal right after submitting the letter of intent.
In case the letter is not well received by RWJF, we will apply for an R01 grant application to NIA. Depending on findings from our exploratory analyses, we will also consider NIMN, NHLBI or NCI.

2) Are you responding to a specific request for proposal (RFP/RFA), program announcement, or other special funding initiative? If yes, which one and how is your Level 2 a good match for it?

We are responding to 2013 Call for Proposals (CFP) of the Changes in Health Care Financing and Organization (HCFO) program funded by Robert Wood Johnson Foundation (RWJF). Grants are awarded on a rolling basis; proposals may be submitted at any time. More detailed information on the CFP is available at http://www.hcfo.org/files/hcfo/cfp_HCFO_2013.pdf

The purpose of the HCFO program is described in the CFP as below, and our proposal, which is to evaluate important current health care policy issues fits well in the program.

“Changes in Health Care Financing and Organization (HCFO) supports policy analysis, research, and evaluation projects that provide policy leaders timely information on health care policy and financing issues, which include “Examining significant issues and interventions related to health care financing and organization and their effects on health care costs, quality and access.”

3) Is this Level 2 being undertaken in response to feedback from a prior external proposal? If so, how does this project address reviewer concerns?

No. Our proposal would be a new application.

4) How does your study compare with projects in similar domains that have been funded by your targeted agency? In particular, how does the scope of your methodology appear similar to other funded projects (in terms of the size and representativeness of the sample, measurement strategies, design and planned analytic approach, etc.)?

Below is a few examples of research projects funded by HCFO (RWJF) in recent years. The priority areas of the HCFO program have included studies on evaluation of policy changes in health care that would affect patient quality and health outcomes. With the recent health care reform legislation, the 2010 Affordable Care Act (ACA), HCFO has funded studies that evaluate the impacts of the ACA. Our proposal also assesses the impact of the ACA expansion in prescription drug benefits, which should be an interesting topic to HCFO. The full list of the projects funded is available at the HCFO Web site, http://www.hcfo.org/grants.

Title: Examining intended and unintended consequences of the hospital readmissions reduction program for Medicare beneficiaries

Abstract: The researchers will identify hospital responses to the Hospital Readmissions Reduction Program (HRRP) and examine whether these responses offset expected savings to
Medicare. Specifically, the researchers will perform a series of logistic regressions in order to analyze any changes in readmission rates and length of hospital stay for Medicare patients admitted for heart attack, heart failure or pneumonia, the three conditions targeted under the HRRP. The researchers will also examine any unintended adverse consequences of the HRRP, including strategic behavior by hospitals that could reduce expected savings to Medicare. The goal of this project is to provide policymakers with a more informed picture of potential hospital responses to an important payment redesign under the Patient Protection and Affordable Care Act (ACA).

Title: Impact of State Policies Supporting Medicare Part D for the Dually Eligible

Abstract: The project assesses two state Medicaid policies - co-payment assistance to reduce cost sharing and beneficiary centered assignment. It examines the impact of these policies for the dually eligible population on health outcomes (health care utilization and sentinel events), beneficiary switching among plans, continuity of drug treatment, and Medicare program costs. It also compares beneficiaries in six states that provide full co-payment assistance to those states without such assistance, and beneficiaries in Maine, the only state with CMS-approved beneficiary centered assignment for dually eligible beneficiaries, to similar beneficiaries in other states. The objective of this project is to inform the Medicare program and state policymakers on the impact of the Part D benefit on dually eligible beneficiaries.

5) What criteria will be used to evaluate your proposal and what do you know about the likely reviewers?

The below is selection criteria described in the CFP of the HCFO program by RWJF. Based on the information provided, we believe that our proposal is a strong candidate for the award.

Policy significance of the health care financing policy or issue being assessed or tested.

⇒ Our proposed study addresses an important policy issue in health care. We propose to evaluate changes in prescription drug benefit policies. As pharmacy therapy plays an increasingly important role in treating health problems, designing drug benefits that ensure access to cost-effective drugs, particularly among high-risk consumers, is an ongoing policy issue. By assessing the relations between drug benefits, drug use, and health outcomes in the elderly, our study will provide information that can be used to design such benefits.

Quality and availability of data to be used and the strength

⇒ We propose to use an almost complete set of Medicare claims data, which can be purchased from the Center for Medicare and Medicaid Services. The strength of these data files is that the claims file contain rich information on all health care service use and spending by a large number of Medicare beneficiaries, which enables researchers to study the impacts of Medicare policy changes on service use and health outcomes of beneficiaries.

Applicant’s experience and qualifications
As discussed in the proposal, our team consists of individual investigators with diverse skills, experience and expertise to perform tasks required for the study. HCFO especially encourages young researchers to team up with senior members and apply for the grant. The primary investigator is a junior faculty member at Penn State, and she develops a research team with senior researchers who have extensive research experience in the proposed research area.

6) **What input/advice/support have you received from your department head and/or college research dean?**

Yes, we have informed Dr. Dennis Shea, the head of the Department Head of Health Policy and Administration, about our intent to submit this proposal. Dr. Shea has agreed to support our efforts by covering the tuition of a graduate student who will work on the project in the fall 2013.

8. **Translational Research Potential:**

   Not applicable.

9. **Letters of Support from All Collaborators**

   See the attached materials

10. **Attach NIH or NSF biosketches**

    See the attached materials
June 17, 2013

SSRI Review Committee
Social Science Research Institute
The Pennsylvania State University
601 Oswald Tower
University Park, PA 16802-6211

RE: Level II Proposal

Dear SSRI Review Committee:

I am very pleased to write in support of Dr. Jung’s Level II Social Science Research Institute (SSRI) proposal titled, “Prescription drug use, health outcomes, and non-drug medical spending in the elderly: Evaluation of changes in prescription drug benefits in Medicare.” This interdisciplinary proposal seeks to explore relations between drug benefit generosity, non-drug medical care use, and health outcomes. Evaluation of the Medicare prescription drug coverage program is an important project to pursue as pharmacy therapy becomes a critical element in treatments for many health conditions particularly for the elderly. The project will also facilitate collaborations among researchers with different disciplines on the development of a grant application for external funding.

As a co-investigator for the project, I will assist in developing a research plan for a grant application in the area of assessing the impact of prescription drug use on health outcomes. I will also provide consultation on research designs and policy implications of the project.

SSRI funding would enhance our ability to secure external funds by allowing us to prepare materials for preliminary data and power calculation through exploratory analyses.
Thank you for your consideration of this grant application.

Sincerely yours,

Douglas L. Leslie, Ph.D.
Professor of Public Health Sciences and Psychiatry
Director, Center for Applied Studies in Health Economics
Department of Public Health Sciences
College of Medicine
Pennsylvania State University
June 17, 2013

Dr. Kyoungrae Jung  
Assistant Professor of Health Policy and Administration  
604 Ford Building  
The Pennsylvania State University  
University Park, PA 16802

Dear Dr. Jung:

I am pleased to write in support of your Penn State Social Sciences Research Institute application “Prescription drug use, health outcomes, and non-drug medical spending in the elderly: Evaluation of changes in prescription drug benefits in Medicare.” This project will extend our existing collaborations on medication adherence among Medicare beneficiaries to investigate relations between drug benefit generosity, non-drug medical care use, and health outcomes. This is an important area to study given the increasing clinical importance of prescription drugs and expansion of prescription drug coverage.

As a co-investigator for the project, I will provide consultation on clinical issues, as well as constructing outcome measures. I will also assist in acquiring or accessing data sets for the development of a grant application for external funding.

I welcome the opportunity to collaborate with you in this important effort.

Sincerely,

A. Marshall McBean, MD, MSc.
KYOUNGRAE JUNG

Position Title
Assistant Professor of Health Policy and Administration

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)

<table>
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<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>YEAR(s)</th>
<th>FIELD OF STUDY</th>
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<tr>
<td>Seoul National University, Seoul, Korea</td>
<td>B.S.</td>
<td>1995</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>Seoul National University, Seoul, Korea</td>
<td>M.P.H.</td>
<td>1999</td>
<td>Health Policy</td>
</tr>
<tr>
<td>University of Minnesota, Minneapolis, MN</td>
<td>Ph.D.</td>
<td>2007</td>
<td>Health Services Research and Policy</td>
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A. Personal Statement

Since receiving a PhD in health policy with concentration on health economics in 2007, my research has focused on examining consumer and provider incentives responding to changes in policies. As PI on an R03 sponsored by the National Institute of Aging, I examined selection incentives by home health agencies under a public reporting program. I have also looked at possible differences in health plans’ incentives to manage prescription drug utilization among their enrollees depending on the breadth of coverage offered by plans. I am currently examining enrollees’ responses to nonlinear pricing in prescription drug benefits. With this focus and experience, I am well suited to lead this proposed project. I will collaborate with Dr. Leslie to address all aspects of analyses of the project.

I also have extensive experience in studying health care utilization, quality of care, and health outcomes using varied large claims data. This proposed project, which will use MCBS data, fits well with my experience. I will collaborate with Dr. McBean, who has clinical knowledge and 30 years of experience with Medicare data file, to explore data files that would be used for an application for external funding.

B. Positions and Honors.

Positions and Employment

1995-1997 Clinical Research Associate, Janssen Korean Limited, Seoul, Korea
1997-1998 Research Assistant, Seoul National University, School of Public Health, Seoul, Korea
1999-2000 Research Associate, Korea Institute for Health and Social Affairs, Health Policy Team, Seoul, Korea
2002-2007 Research Assistant, University of Minnesota, School of Public Health, Division of Health Policy and Management and Research Data Assistance Center (ResDAC), Minneapolis, MN
2006 Instructor, University of Minnesota, School of Public Health, Division of Health Policy and Management, Minneapolis, MN
2007-present Assistant Professor, The Pennsylvania State University, Department of Health Policy and Administration, University Park, PA

Other Experience and Professional Memberships

2006-present AcademyHealth
2006-present International Health Economics Association
2006-present American Society of Health Economists
2007-present Research Faculty, Center for Health Care and Policy Research, Pennsylvania State University, State College, PA
Honors
1991-1994 Merit Award, College of Pharmacy, Seoul National University
1995 Cum Laude Graduate, College of Pharmacy, Seoul National University
1997-1998 Merit Award, School of Public Health, Seoul National University
1999 Summa Cum Laude Graduate, School of Public Health, Seoul National University
1999 Best Thesis Award, School of Public Health, Seoul National University
2000-2001 Graduate School Fellowship, University of Minnesota
2006 Juran Dissertation Fellowship Finalist, Juran Center for Leadership in Quality
2006 Professional Development Grant, School of Public Health, University of Minnesota
2007 Delta Omega Phi (The Honorary Public Health Society)
2008 Most Outstanding Abstract, AcademyHealth
2012 The Fran and Holly Soistman Faculty Development Endowment, Penn State University

C. Selected peer-reviewed publications (in chronological order).


McBean, M., Jung, K., Virnig, B., Improved Care and Outcomes among Elderly Medicare Managed Care Beneficiaries with Diabetes, American Journal of Managed Care, 2005, 11:4, 213-222


D. Research Support.

**Completed research support**
1R03AG035098-01 (Jung) 5/10 - 4/13 NIH/NIA

**Public Reporting and Market Area Exit Decisions by Home Health Agencies**

The aim of this project is to examine the impact of a public reporting program on access to home health care among socio-economically disadvantaged populations. Specifically, this project examines whether home health agencies discontinue service to market areas with disadvantaged populations after public reporting.

Role: Principal Investigator

XXX (Jung) 6/08 - 5/11
Social Science Research Institute/Pennsylvania State University

**Public Reporting and Home Health Care Quality**

This project examines whether home health care agencies have incentives to improve quality under Home Health Compare, a Medicare public reporting program in home health care.
BIOGRAPHICAL SKETCH
Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FOUR PAGES.

NAME
Leslie, Douglas L.

POSITION TITLE
Professor, Public Health Sciences and Psychiatry

eRA COMMONS USER NAME (credential, e.g., agency login)
DLLESLIE

EDUCATION/TRAINING
(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>MM/YY</th>
<th>FIELD OF STUDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Virginia, Charlottesville, VA</td>
<td>B.A.</td>
<td>05/90</td>
<td>Economics</td>
</tr>
<tr>
<td>Yale University, New Haven, CT</td>
<td>Ph.D.</td>
<td>05/98</td>
<td>Economics</td>
</tr>
</tbody>
</table>

A. Personal Statement
The proposed project would investigate …. My broad background in health economics and health services research, with specific training and experience in working with large databases, provide me with the expertise to successfully collaborate on the proposed project. As a Professor at the Penn State College of Medicine and Director of the Center for Applied Studies in Health Economics at Penn State, I have extensive experience with working with administrative and clinical databases to study health care costs, services use, and their correlations with patient outcomes. As PI or co-Investigator on several previous NIH-funded grants, I have considerable experience collaborating with multi-disciplinary teams to explore issues of how patient and health care system factors affect clinical outcomes and costs.

B. Positions and Honors

Positions and Employment
1997 – 1999  Associate Research Scientist, Department of Psychiatry, Yale School of Medicine (YSM), New Haven, CT
1997 – 2007  Mental Health Economist, Northeast Program Evaluation Center, West Haven, CT
1999 – 2006  Assistant Professor, Department of Psychiatry, YSM, New Haven, CT
2000 – 2006  Assistant Professor, Department of Epidemiology and Public Health, YSM, New Haven, CT
2006 – 2007  Associate Professor, Department of Epidemiology and Public Health, YSM, New Haven, CT
2006 – 2007  Associate Professor, Department of Psychiatry, YSM, New Haven, CT
2007 – 2009  Associate Professor, Department of Health Administration and Policy, Medical University of South Carolina, Charleston, SC
2009 – Present Professor, Department of Public Health Sciences, Penn State College of Medicine, Hershey, PA
2011 – Present Director, Center for Applied Studies in Health Economics, Department of Public Health Sciences, Penn State College of Medicine, Hershey, PA

Other Experience and Professional Memberships
2005 – Present  Charter Member, American Society of Health Economists
2007 – Present  Standing member, NIMH SRSP review committee
2008 – Present  Editorial Board, Medical Care Research and Review
2011 – Present  Member, IOM Committee on the Assessment of Ongoing Efforts in the Treatment of PTSD

Honors
2001, 2002  MarketScan Investigator Award, The MEDSTAT Group
2005  Excellence in Mental Health Policy and Economics Research Award, ICMPE
2006  Research Mentorship Award, Interdisciplinary Postgraduate Training in Mental Health Policy and Economics Research, International Center for Mental Health Policy and Economics
2008  Academic Co-Chair, 14th NIMH Research Conference on the Economics of Mental Health
2008  Medical University of South Carolina Scholar of the Year, College of Health Professions
C. Selected Peer-reviewed Publications (From a total of over 80)


22. Petrakos IL, Leslie DL and Rosenheck RA. “The use of antidepressants in alcohol dependent veterans.”


60. Leslie DL, Mohamed S, and Rosenheck RA. "Off-label use of antipsychotic medications in the Department of Veterans Affairs." *Psychiatric Services* 2009; 60(9): 1175-1181.


64. Gore M, Zlateva G, Tai KS, Chandran AB and Leslie D. "Retrospective evaluation of clinical characteristics, pharmacotherapy and healthcare resource use among patients prescribed pregabalin or duloxetine for..."


D. Research Support

Ongoing Research Support

No Number Assigned (Leslie-Meyer) 3/1/2012-6/30/2013

Alkermes

The Effectiveness of XR-NTX for Opioid Dependence in a Large Multi-State Treatment Network
The goal of this project is a retrospective data analysis of health records to examine the utilization of Vivitrol in the treatment of patients with opioid and/or alcohol dependence compared with other treatment modalities.

Role: PI

1R01MH097298-01 (Leslie) 9/20/2012-8/31/2015
NIH/NIMH

The Effects of State and Federal Insurance Policies on Quality of Care for Autism
The goal of this project is to examine the effects of state Medicaid HCBS waivers on access to care, satisfaction and family burden among Medicaid-insured children with ASD and their families.

Role: PI

VA Medical Center Grant (Brandt) 11/01/07–10/31/2013
Department of Veterans Affairs
Women Veterans Cohort Study
The goal is to investigate demographic, clinical, and healthcare utilization factors among the cohort of women veterans of OEF/OIF who have utilized VA clinics.

Role: Site PI

1R01MH096711-01 (Wang) 9/12/2012-7/31/2015
NIH

Do Access Barriers to Autism Care Persist Despite Autism Insurance Mandate?
The goal of this project is to use post-mandate private insurance claims data to measure actual changes in autism service use, costs and health benefits after autism insurance mandates.

Role: Co-Investigator

1 R01 MH 091453-01 (Leslie) 9/23/2010-6/30/2015
NIH/Yale University

Effective and Cost Effectiveness of Peer Mentors in Reducing Hospital Use
This study will be extremely useful in informing future policy and programmatic decisions related to the promotion of evidence-based practices in the care of individuals with serious mental illnesses.

Role: Site PI

1R01 NR012737 (Jablonski) 4/1/2011-2/28/2015
NIH

Reducing Care-Resistant Behaviors during oral Hygiene in Persons with Dementia
The goal of this study is to evaluate the efficacy of the mouth intervention for reducing Care-Resistant Behaviors in persons with dementia.

Role: Co-Investigator

No Number Assigned (Leslie) 10/1/2010-9/30/2013
Veterans Affairs (VA)

A Comparison of Fidelity Assessment Methods
Role: PI

1R01DA032881-01A1 (Stein) 7/1/2012-6/30/2015
NIH/RAND Corporation

Opioid Agonist Treatment Expansion in Medicaid: The Role of Buprenorphine
The proposed project would use data from state Medicaid programs to examine factors affecting the diffusion of buprenorphine for the treatment of opiate abuse, both inside and outside of traditional substance abuse treatment settings.

Role: Site PI

1 R01 NR012242 (Kolanowski) 9/1/2010-6/30/2015
NIH

RESERVE for Delirium Superimposed on Dementia
The goal of this project is to test the efficacy of an intervention to prevent delirium in elderly patients with dementia by means of a randomized controlled trial.

Role: Co-Investigator
The Penn State Clinical and Translational Science Institute

The goal of Penn State CTSI is an engaged and responsive health science research and education enterprise that delivers on the promise of improved health.

Role: Co-Director, Education Core Curriculum

Career Development Program in Women’s Health Research at Penn State

The purpose of this BIRCWH project is to provide mentored research career development for junior faculty members, known as BIRCWH Scholars, who are conducting interdisciplinary research on women’s health or on sex/gender differences in health.

Role: Mentor

Completed Research Support

Economic Production Functions of Schizophrenia Treatment

The goal of this project is to study the treatment of schizophrenia across various patterns of care.

Role: Principal Investigator

Patterns of Service Use and Costs Associated with Autism

Grant supports secondary dataset analyses (private and Medicaid sources) aimed at understanding time trends and priorities associated with the costs of care for autism and related disorders.

Role: Principal Investigator

Mechanisms of Action and Outcome in Peer Support Groups

The goal is to determine cost estimates for adding peer-led vs. clinician-led groups to treatment plans to determine comparative costs of these two interventions.

Role: Site PI
BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2. Do not exceed four pages.

NAME
A. Marshall McBean

POSITION TITLE
Professor

eRA COMMONS USER NAME
mmcbean

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)

<table>
<thead>
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<th>INSTITUTION AND LOCATION</th>
<th>DEGREE</th>
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<tbody>
<tr>
<td>Yale College, New Haven, CT</td>
<td>B.S.</td>
<td>1964</td>
<td>Biology</td>
</tr>
<tr>
<td>Harvard Medical, Boston, MA</td>
<td>M.D.</td>
<td>1968</td>
<td>Medicine</td>
</tr>
<tr>
<td>University of London School of Hygiene &amp; Tropical Medicine</td>
<td>M.Sc.</td>
<td>1976</td>
<td>Social Medicine</td>
</tr>
</tbody>
</table>

A. Personal Statement.

I am board certified in Preventive Medicine, and a Professor in the Division of Health Policy and Management in the School of Public Health at the University of Minnesota. I have over 35 years of research experience, the last 21 of which has focused on the analysis of secondary databases, primarily the Medicare and Medicaid data. I also have over 12 years experience training other researchers to use Medicare administrative data. Therefore, I have great knowledge of the strengths and weaknesses of the data as they would be used in model development and secondary data analysis.

B. Positions and Honors.

Positions and Employment:
1968-1970 Intern & Resident, Boston City Hospital (Harvard Service) Boston, MA, Internal Medicine
1970-1971 Epidemic Intelligence Service (EIS) Officer, Smallpox Eradication Program, Center for Disease Control (CDC), Atlanta, GA
1971-1974 Medical Epidemiologist, OCEAC (Organization for the Coordination of fight against the Endemic Diseases in Central Africa), Yaounde, Cameroun
1975-1976 Fellow, Harvard Center for Community Health and Medical Care, Boston, MA
1976-1978 Commissioner, Vermont State Health Department, Burlington, VT
1978-1987 Associate Professor, Department of Health Policy and Management, Johns Hopkins School of Hygiene and Public Health, Baltimore, MD
1987-1994 Medical Researcher and The Chief, Epidemiology Branch, Division of Beneficiary Studies, Office of Research, Health Care Financing Administration, Baltimore MD
1994-1995 Visiting Professor, School of Public Health, University of Minnesota, Minneapolis MN
1997-1998 Division Head, Health Management & Policy, University of Minnesota, Minneapolis, MN
1997- Professor, School of Public Health, University of Minnesota, Minneapolis, MN

Honors and Awards:
Phi Beta Kappa
Sigma Xi
Delta Omega (Public Health Honor Society)
HCFA Administrator’s Award - 1991
U.S. Public Health service Commendation Medal - 1992
DHHS Secretary’s Award for Distinguished Service - 1995

C. Selected peer-reviewed publications.

2. McBean AM, Gornick M. Differences in the use of surgical services by race among Medicare


D. Research Support.

Ongoing Research

HHSM500-2005-000271 TO3 McBean (PI) 09/28/08-09/29/13
Center for Medicare and Medicaid Services (CMS)
Research Data Assistance Center (ResDAC)
The goal of ResDAC (Research Data Assistance Center) is to assist CMS in increasing the number of new researchers skilled in accessing and in use CMS data for studies, which will improve the Medicare and Medicaid programs and add value to current CMS activities. Role: PI

ARRA / T.O.003, HHSM-500-2005-000271 04/01/10-09/30/12
Center for Medicare and Medicaid Services (CMS)
Research Data Assistance Center (ResDAC) Comparative Effectiveness Research (CER)
The goal of ResDAC (Research Data Assistance Center) is to assist CMS in increasing the number of new researchers skilled in accessing and in use CMS data for projects relating to CER, which will improve the Medicare and Medicaid programs and add value to current CMS activities. Role: PI

500-2005-000271, TO 2 (McBean) 09/01/11-12/31/12
Centers for Medicare and Medicaid Services (CMS)
ACA Section 10332 Technical Assistance Contract
The proposed contract will provide CMS data support to Qualified Entities (QEs)in using Medicare claims data. In addition, the team will provide education and training opportunities focused on better understanding Medicare claims data tailored to QEs. Role: PI
**Completed Research**

1R21DK081055-01 (McBean)  09/01/09-08/31/11
NIDDK
Measuring the Impact of Rapid Expansion of MIST Procedures for BPH
The major goal of the project is to understand how physician-related factors, as well as patient, organizational and societal factors interact in the diffusion of the MIST procedures and explain how these interactions affect the disparities during the diffusion of the new procedures. Role: PI

200-2011-M-40657 (McBean)  08/22/11-12/31/11
CDC
Introduction to the Use of Medicare Data for Public Health Research
The workshop will familiarize the CDC audience with the use of Medicare administrative data for research. Role: PI

HHSM-500-2005-00271  McBean (PI)  09/27/05-01/31/2011
CMS DHHS
MRAD Task Order 1
Conducting analytic studies designed to better understand the nature of chronic disease among Medicare beneficiaries and to improve the care of these populations. The 723 database will serve as the data source for the analytic studies to be conducted under this contract. Role: PI

CA098974  McBean (PI)  09/01/04-08/31/09
NIH, National Cancer Institute
Health Service Use in the elderly with Cancer
Elderly persons with newly diagnosed cancer are under great personal stress, and they face a potentially rapidly changing relationship with health care professionals and the system. Prior to the diagnosis of cancer, many of these people will have routinely used recommended clinical preventive services and will have been followed appropriately for other chronic conditions such as diabetes, hypertension and other heart disease. However, because in their change in health status, treatment, and use of new services they may fail to continue to use the recommended services and treatment. This study will compare the use of recommended preventive and chronic disease treatment services between elderly persons who are newly diagnosed with cancer to those who do not have cancer. Role: PI

NO1-DK-7-5002  Gilbertson (PI)  02/07-04/03/10
MMRF prime NIH
United States Renal Data System (USRDS)
The major goal of this project is to provide biostatistical, epidemiological and clinical expertise to development and implement innovative health policy studies using the United States Renal System (USRDS) databases. Role: Co-Investigator