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The Center and its Charter

The Duke-Margolis Center for Health Policy initiated operations in January 2016. Locations in Durham, NC and Washington, DC integrate the expertise of Duke University’s scholars and academic health system with an established team experienced in convening stakeholders and conducting policy analysis.

The ability to gather and analyze evidence across the spectrum of policy to practice supports the **triple aim** of health care:

- Improving the experience of care
- Improving the health of populations
- Reducing per capita cost

**Fueled by Duke University’s entrepreneurial culture, Duke-Margolis will harness Duke’s broad multidisciplinary capabilities to deliver transformative impact.**
The Mission

This strategic plan honors the Center’s interdisciplinary, multidisciplinary design and its education, research, and patient care. These capabilities, combined with an experienced team of policy analysts and researchers, located in Washington, DC, sets the stage for Duke to be a leader in policy impact.

The plan focuses on generating new knowledge and its implementation and application to pressing policy problems in healthcare delivery, payment and biomedical innovation.

In order to formulate a comprehensive initial strategy, and define the work we will undertake in FY 2017, the Center has listened to many voices at Duke and engaged potential collaborators around the country and around the world.

Improve health and the value of health care by developing and implementing evidence-based policy solutions.
Research Portfolio

**Healthcare Delivery Reform**
- Healthcare Reform Policy Evidence Hub
- Empirical Analysis for Healthcare Reform
- Healthcare Reform Leadership
- Clinical Pathway Reform

**Biomedical Innovation**
- Biomedical Innovation Policy Evidence Hub
- Regulatory Policy for Biomedical Products
- Linking Biomedical Products to Value

**Education & Workforce Development**
- Undergraduate policy education and pathways
- Graduate Policy Education across disciplines
- Executive Education: Providers, Payers, Industry
Healthcare Delivery Reform

Environment
Portfolio
Immediate Opportunities
Future Opportunities
Without effective solutions, clinician burdens are increasing, with more providers reporting that they are overwhelmed by care coordination, documentation, and compliance requirements.

Recent reforms have aimed to encourage a shift away from fee-for-service to value-based financing approaches, including recent policy changes in the U.S. at the federal level (Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), IMPACT Act, and Affordable Care Act), state level (Medicaid), and the adoption of these models by private insurers. But all these efforts are occurring in an environment of uncertainty due to limited evidence on the most effective approach to reform.

Current environmental, demographic and fiscal pressures in the United States and abroad make healthcare delivery reform a central theme for Duke-Margolis. Healthcare systems and governments are embracing innovation toward more personalized, prevention-oriented care, while facing growing pressure to address rising costs. At the same time, the system is burdened by the demographic challenge of increasing numbers of patients with complex healthcare needs, including multiple chronic conditions requiring team-based care and coordination.

**Systems in the US and around the world have not solved the question of how to pay for care in a way that encourages a shift to high-value, innovative care and how to empower patients and consumers to help lead it.**
Portfolio

Projects in this portfolio draw on expertise from across Duke University to create the research and data infrastructure necessary for empirical analysis of challenging healthcare delivery and payment reform questions.

Working with the Duke Clinical Research Institute and other collaborators, Duke-Margolis will create an Evidence Hub that will bring together expertise, best practices, and multiple data sources under shared governance structures for data curation and use. This resource will empower faculty and research teams to address key policy questions related to health care delivery, with particular attention to payment reform.

The Center will also collaborate with multiple entities within Duke Health to create structures necessary for piloting new ideas to deliver, finance, and regulate health care. The work will be at multiple levels, from supporting Duke Health’s strategic direction and leadership in care delivery, to state and regional improvements, to national policies, to international collaborations.

Immediate Opportunities

• Multicenter payment reform evaluation

• Use Duke data resources to analyze prominent payment reforms

• Support Duke strategy and care redesign, preparation for MACRA and Medicaid reform, and to lead further state and national efforts in payment reform

• Evidence-driven quick turnaround feedback on MACRA implementation

• Primary-specialty care collaboration and coordination

• Digital health approaches to preventive, well-coordinated, and efficient care

• Implementing accountable care worldwide

• Health care payment reform to support population health improvement initiatives
Future Opportunities

- Build distributed data infrastructure with other institutions to facilitate comprehensive data and empirical analysis of reforms to evaluate effectiveness from multiple perspectives (patient, physician, payer, societal) and identify unintended consequences

- Policy reforms and support for healthcare organizations shifting from a focus on service lines to a focus on patient-centered care pathways

- Evaluating impact of care teams including community health workers and other low-cost, population-based approaches to care and payment

- Efficient, effective, and consistent data sharing and quality measurement to support better care

- Research on payment and benefit design that incorporate the patient perspective
Biomedical Innovation Policy & Evidence Development

Environment
Portfolio
Immediate Opportunities
Future Opportunities
Still, unmet medical need remains. Many chronic diseases and acute conditions lack adequate therapies and cures, forcing policy makers to grapple with practical approaches for incentivizing innovation and development while facilitating access to leading-edge medical technologies in ways that maximize value and outcomes.

Scientific advances in basic disease and systems biology, genomics, proteomics, metabolomics and immunology are driving a robust drug and therapeutic development pipeline that increasingly includes targeted, more effective and even curative specialty therapies, as well as more advanced medical devices. In 2015 FDA approved 45 novel drugs, 36 percent of which are first-in-class. At the same time, biomedical innovation is challenged by many of the same forces driving the need to reassess delivery and payment models, including the high prices of many new therapies.

Better approaches are needed for encouraging investment in areas of unmet need, reducing the time and cost of medical product development, and supporting high value evidence-based uses of drugs, devices, and other technologies.
Portfolio

Projects in this portfolio of work address the development, regulation and use of medical products and technologies. Duke-Margolis will create an evidence and policy hub aimed at developing policies and approaches to support cost-effective continuous learning to improve safe, high-value uses of drugs, devices, and other technologies. Through collaborations with patients, providers, regulators, payers, and the pharmaceutical and medical device industry, the biomedical evidence and policy hub will support improved decision-making across the healthcare system. The primary focus of this work will be on increasing the value of biomedical innovation to patients – including both better health outcomes and lower overall health care costs.

This portfolio also explores approaches to modernize the drug development process and advance the adoption of new tools for regulatory decision-making. Policy solutions are needed to gain ground in implementing drug development tools such as biomarkers and clinical outcome assessments, and to adopt methods incorporating the voice of the patient in both drug development and regulatory decision-making.

Lastly, Duke-Margolis will support the development and evaluation of new payment models and contracting approaches related to innovative biomedical projects that support better outcomes and higher value care to patients.
**Immediate Opportunities**

- Economic incentives for addressing antimicrobial resistance
- Value assessment framework advancement
- Advancing regulatory and payment uses of real world evidence
- Utilizing electronic health information to address critical questions about product safety and effectiveness
- Improving biomarker and surrogate endpoint development, and accelerating drug development
- Innovative solutions to deter opioid abuse
- Improving regulatory approaches involving medical technologies, such as risk evaluation and mitigation strategies (REMS) and the regulation of “off-label” promotion

**Future Opportunities**

- Evaluate and inform Medicare Part B drug payment reforms
- Explore and pilot innovative value-based payment models for medical products
- Evidence generation and innovative payment around curative treatments
- Building the knowledge base to advance regulatory guidance development
- Piloting new approaches to medical product evaluations
- Exploring data and methods that better meet clinician and patient information needs
- Improving approaches for collecting patient preferences during drug development
Education and Workforce Development
Environment

With major changes occurring in both health care and biomedical innovation, the skills required to succeed and thrive as a health care provider, industry leader, or policymaker must change as well. Clinicians and product developers need to understand the operational and financial implications of new payment models and regulatory approaches, as well as how to drive effective change in the healthcare landscape. In a complex regulated environment where multiple individuals and organizations are responsible for delivering quality care, new skills and collaborations must be established to drive needed policy changes.

Students, faculty and working professionals at all levels have expressed remarkable eagerness to work with Duke-Margolis to improve health policy education and workforce development.

Portfolio

Duke-Margolis will implement a three-pronged approach for Duke’s leadership in education and competency development related to transforming health care and biomedical innovation at the undergraduate, graduate, and continuing and executive education levels. For undergraduates, the Center will focus on increasing opportunities to gain exposure to the field of health policy and collaborative curricular pathways and expanded mentored research opportunities for undergraduates interested in health policy. For Graduate and Professional students across multiple disciplines, Duke-Margolis will work collaboratively across the university and with neighboring institutions to provide health policy course offerings and research opportunities, as well as exploration of collaborative policy-focused postdoctoral fellowships.
Undergraduate

As a first step, we have arranged for additional sections of PUBPOL 165 (Introduction to the United States Healthcare System) to be offered in the coming school year, thereby expanding the academic gateway for undergraduates with an interest in exploring health policy.

Duke-Margolis also proposed and gained funding for a Duke University Bass Connections course, including faculty from Law, Policy, Nursing and the Duke-Margolis policy staff in Washington, DC. Applications and expressions of interest have already been received from undergraduate, graduate and medical students for a course slated to begin in January 2017.

Graduate and Professional

Graduate and Professional education is a linchpin for the development of future policy-aware professionals. As a university-wide enterprise designed to attract and mentor PhD and medical students doing health policy research, Duke-Margolis is collaborating closely with the Sanford School of Public Policy, the School of Medicine, and the new Center for Population Health Sciences on curricular innovations and opportunities to expand health policy course offerings for graduate and professional students. These efforts will serve as pilot projects for an aspirational goal of a Duke University Master in Health Policy, while allowing us to gauge student demand, appropriate structure for accreditation, and ongoing resource requirements. In the interim, we are exploring postdoctoral fellowship opportunities in collaboration with a number of Duke Programs (e.g. DCRI, DCI).
External Partnerships

The center is also actively exploring new collaborations with the University of North Carolina’s Eshelman School of Pharmacy to provide new educational opportunities in pharmaceutical and regulatory policy as well as clinical leadership in accountable care for PhD and PharmD students. Similar discussions with Dell Medical School at the University of Texas are underway.

Executive Education

Finally, the Center is developing executive education offerings, such as working with associations and private industry to create a network of midlevel executives engaged in ongoing education in health policy and corporate leadership, including participation in a year-long collaborative research project.

Immediate Opportunities

• Create a curricular pathway and expand mentored research opportunities for undergrads curious about health policy

• Expand engagement of Duke-Margolis faculty to serve as mentors for medical students’ third-year research projects

• Margolis fellows program in public policy as a “super-concentration” for graduate students in the Sanford MPP program; develop this concentration as a differentiator for Duke MPP program recruitment

• Addition of health policy modules to the Physician Leadership Academy, the Duke Clinical Leadership Program, and other professional education programs at Duke

• Offering the “Business & Policy in Medicine” course for School of Medicine students in their third and fourth years

• Working with UNC Eshelman School of Pharmacy to provide policy project opportunities and guidance for PhD and PharmD graduate students
Future Opportunities

• Collaborate on faculty recruitment to help fill curricular gaps

• Strive to make the Center a university-wide asset to help in the recruitment and mentoring of PhD and MD students doing health policy research

• Build on current projects to expand executive education offerings

• Continue to develop undergraduate course-based and experiential learning opportunities

• Collaborate with UNC Eshelman School of Pharmacy on formal fellowship program
2017 Goals

1. Discovering and deepening a mutually beneficial connection to Faculty and Departments in the Trinity College of Arts and Sciences and the Pratt School of Engineering.

2. Pursuit of at least three, and award of one major collaborative grant from prominent public and nonprofit sources.

3. Pursuit of at least two substantial grants from the private sector.

4. Governance model, and Memorandum of Understanding, and articulation of initial projects to solidify joint infrastructure and collaboration with DCRI, the Center for Population Health, and Duke Health.

5. Participation in the recruitment of 2-3 joint faculty hires.

6. Ten candidates in the Sanford Master of Public Policy accepted as health policy focused Margolis Fellows.

7. Finalize EAB and host inaugural meeting.

8. Public Launch Events in Durham, NC and Washington, DC.
External Advisory Board

Approximately fifteen senior advisors have been or are being recruited to serve on the board, bringing experience from policy-relevant public and private sectors including healthcare payers, legislative, biomedical, foundation, and high technology.

The board’s advisory function will be served predominantly through participation in bi-annual face-to-face meetings, alternating between the Washington, DC and Durham, NC locations, but advisors may also provide occasional advice for particular initiatives.
Membership

Membership in the Duke-Margolis Center is open to Duke Faculty of all ranks. The specific advantages and responsibilities of membership will evolve over the course of FY 2017, but inclusion in the community and opportunity to contribute to (and receive authorship or other credit) for work product has been viewed favorably by a diverse group of affiliated scholars.

Executive Team

**Mark B. McClellan**  
*Director and Robert J. Margolis, MD, Professor of Business, Medicine and Health Policy*

Mark B. McClellan, MD, PhD, directs the Duke-Margolis Center, building on a distinguished career in academia and government focusing on health outcomes research, payment reforms, evidence-based policy methods, and drug and device innovation. In addition, he leads the Center’s healthcare delivery reform portfolio, which includes policy and data strategies for payment reform, accountable care organizations.

**Gregory W. Daniel**  
*Deputy Director and Clinical Professor, Fuqua School of Business*

Gregory W. Daniel, PhD, MPH, RPh, directs the Duke-Margolis office in Washington, DC. He leads the Center’s pharmaceutical and medical device policy portfolio, which includes policy and data strategies for improving development and access to innovative pharmaceutical and medical device technologies. His expertise spans post-market evidence development to support increased value, improving regulatory science and drug development tools, optimizing biomedical innovation, and supporting drug and device payment reform.

**Victoria Christian**  
*Chief Operating Officer*

Victoria Christian directs the Center’s operations and strategic alignment. She has held executive leadership roles in clinical and translational research for pharmaceutical, biotechnology, CRO, and academic organizations.

**Ellen de Graffenreid**  
*Director of Communications*

Ellen de Graffenreid, MA, MBA, directs the center’s strategic communications, marketing and media relations. For more than fifteen years, she has led marketing and communications for organizations in higher education and academic medicine, leading cross-functional teams and serving as spokesperson and chief communications officer.
During the year leading up the Center’s formation, Duke President Richard Brodhead, Drs. Kornbluth and Washington engaged numerous faculty across Duke’s campus.

These faculty have contributed to the Center’s initial strategy, and continue to lead and serve programs from their home schools and departments:

**Founding Faculty**

**Mark B. McClellan, MD, PhD**, Director of the Center, and Professor of Business, Medicine, and Health Policy.

**Gregory W. Daniel, PhD, MPH**, Deputy Director of the Center and Clinical Professor in the Fuqua School of Business. Dr. Daniel is also a Senior Adviser to the Reagan-Udall Foundation and Adjunct Associate Professor in the UNC Eshelman School of Pharmacy.

**Lesley H. Curtis, PhD**, professor in medicine at the Duke University School of Medicine and directs the Center for Pragmatic Health Services Research in the Duke Clinical Research Institute, and the Center for Population Science in the School of Medicine.

**Adrian Hernandez, MD**, is a Professor of Medicine at Duke University, and Associate Director of the Duke Clinical Research Institute.

**Eric Peterson, MD, MPH**, Fred Cobb Distinguished Professor of Medicine in the Division of Cardiology, and the Executive Director of the Duke Clinical Research Institute.

**Thomas Owens, MD**, Vice President for Medical Affairs and Chief Medical Officer for the Duke University Health System. He is Associate Professor of Medicine and Pediatrics in the School of Medicine.

**Barak Richman JD, PhD**, Edgar P. and Elizabeth C. Bartlett Professor of Law and a Professor of Business Administration at Duke University. Richman also is on the Health Sector Management faculty at Duke’s Fuqua School of Business and is a Senior Fellow at the Kenan Institute for Ethics.

**David Ridley, PhD**, Dr. and Mrs. Frank A. Riddick Associate Professor of the Practice of Business and Economics. He is also the Faculty Director of the Health Sector Management program at Duke University’s Fuqua School of Business.

**Donald Taylor, PhD**, Professor of Public Policy at Duke University Sanford School of Public Policy, with academic appointments in Community and Family Medicine and Nursing. He is an Affiliate in Duke’s Initiative in Science and Society and Global Health Institute, and faculty member in the Duke Clinical Research Institute and Duke Cancer Institute.

**Peter Ubel, MD**, Madge and Dennis T. McLawhorn University Professor of Business, Medicine, and Public Policy at Duke University and Associate Director, Health Sector Management at the Fuqua School of Business.

**Krishna Udayakumar, MD, MBA**, Associate Professor of Global Health and Medicine at Duke University serves as Director of Duke’s Center for Global Health Innovation.
Offices

Durham, NC

In January 2017, the Duke-Margolis Center will move from its temporary home in Fuqua’s Wesley Alexander Magat Academic Center, into the new JB Duke Hotel and Thomas Executive Conference Center being built at the edge of Duke’s West Campus. The Center faculty and staff will occupy 5,200 ft\(^2\) of office, collaborative, and meeting space, and have access to the 20,850 ft\(^2\) Conference Center for convening workshops, expert advisory meetings and larger events at Duke.

Washington, DC

Also early in 2017, Duke University will move its offices in Washington, DC to a single space where Duke-Margolis faculty and staff will be able to interact regularly with other Duke faculty and staff (both visiting and those working in DC), utilize conference space and technology optimized for a wide variety of policy discussions and interactions, and easily access lawmakers and staff on Capitol Hill. Duke will be an anchor tenant for a space of 3,412 square feet at 1201 Penn (1201 Pennsylvania Avenue). This location will be visible within the DC policy community and help raise Duke University’s profile in Washington.
For More Information

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