



March 24, 2016

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## Advocacy News

### Urge Your Member of Congress to Co-Sponsor the Treat and Reduce Obesity Act

March is National Nutrition Month and, as part of the Endocrine Society's centennial [celebration](#), we are using this month to raise awareness of how hormones influence obesity. Currently, we are working with Congress on bipartisan legislation known as The Treat and Reduce Obesity Act ([H.R. 2404/S. 1509](#)) and we need your help in encouraging your Members of Congress to co-sponsor this legislation. Please click [here](#) to join the Endocrine Society's campaign.

If passed, this legislation would:

- Expand the Medicare benefit for intensive behavioral counseling by allowing additional types of health care providers to offer this service.
- Provide coverage of prescription drugs under Medicare Part D for chronic weight management to individuals who are obese or overweight with one or more co-morbidities.

**Take Action:** Joining our [campaign](#) is quick and easy. Our new online campaign will provide you with a letter and will send it to your Congressional delegation for you.

### Additional Resources

[Letter to Senate on Obesity Prevention](#)

[Facts & Figures: Obesity](#)

## **Endocrine Society Advocacy Victory: HHS Proposes Medicare Coverage for the National Diabetes Prevention Program**

The Secretary of the Department Health and Human Services (HHS), Sylvia Burwell, announced that the Centers for Medicare and Medicaid Services (CMS) plans to provide coverage for the National Diabetes Prevention Program (NDPP). While this proposal still must go through a public comment period, it is expected to go into force before President Obama leaves office. This is a major victory for the Society and for the broader diabetes community. The NDPP is an evidence-based lifestyle intervention program that has been shown to reduce or delay the onset of diabetes by 71% in the Medicare population. NDPP promotes weight loss and encourages increased physical activity and healthier eating habits for people with prediabetes via a core 16-session lifestyle intervention: one hour a week, in a group setting, directed by a lifestyle coach. Studies show that Medicare saved \$2,650 for each individual who was enrolled in a program, as individuals were able to substantially reduce their risk for future diabetes.

Over the past five years, the Endocrine Society has been a leading advocate calling for Medicare coverage of NDPP. We met with both Congressional offices and federal agencies and we worked with other diabetes advocates to share our message. We are pleased with HHS' decision to provide coverage and look forward to working with the agency and with coalition partners to ensure that this program has a measurable impact on the lives of people with prediabetes. It is not yet clear how Medicare will reimburse for these services, as it will be delineated in future rulemaking; the Society will provide comments to CMS on this issue and will inform its members as we move forward in ensuring that people with prediabetes have access to these programs.

While the Secretary's actions will ensure coverage for Medicare recipients, we believe that the program must be available to all people with prediabetes. The Endocrine Society, and other diabetes stakeholders, [submitted a letter](#) to the Congressional Appropriations Committees requesting \$25 million in funding for the NDPP for Fiscal Year 2017 to allow the Centers for Disease Control and Prevention to expand the program to additional sites. This request follows recent successes to expand funding for the NDPP which doubled from \$10 million to \$20 million in FY 2016.

## **Society Releases Policy Recommendations to Improve Diabetes Care**

The Endocrine Society has released a set of policy recommendations prioritizing ways to improve care for people with diabetes as federal agencies implement the Affordable Care Act (ACA) and

reshape healthcare delivery. These [recommendations](#), which will be published in the April issue of the *Journal for Clinical Endocrinology and Metabolism*, state that in order to provide integrated care for people who have diabetes and may be at risk of developing a myriad of related medical problems, the U.S. health care system needs to continue researching and building effective multidisciplinary care team models.

The Endocrine Society's recommendations include the following:

- Prevention and management of diabetes and prediabetes should be better integrated into health systems as well as community and employer-based health programs.
- Reimbursement should be reformed to reward health care providers for providing integrated, comprehensive care that complies with industry guidelines for best practices.
- An increase in federal funding and other financial support is needed for research to address gaps in knowledge about diabetes care and promote the development of next-generation treatment options.
- The U.S. Food and Drug Administration and Centers for Medicare and Medicaid Services must accelerate the approval process for new treatments that address unmet needs in diabetes care.

The Society's analysis of the challenges and opportunities created by the implementation of the ACA reflect that without enough trained health care providers, it will be challenging to provide this level of care. The Endocrine Society's 2014 [workforce analysis](#) found that the supply of endocrinologists who treat adults will outpace the growing demand for their services until at least 2024. This could mean longer waits for appointments for people with diabetes and other endocrine conditions. Therefore, the recommendations also include the need to train more endocrinologists and primary care providers to adequately support integrated care teams.

The recommendations also note that the number of people diagnosed with diabetes is likely to rise as more people gain health insurance coverage through the ACA. One study found a 23 percent increase in Medicaid patients diagnosed with diabetes in states that adopted the ACA Medicaid expansion, compared to a 0.4 percent increase in states that did not. About one in four Americans with diabetes is undiagnosed, so expanded access to care is likely to lead to earlier diagnosis and treatment.

The Society's recommendations will be shared with members of Congress. Should you be interested in learning more about how you can get involved with the Society's diabetes advocacy activities, please contact Meredith Dyer at [mdyer@endocrine.org](mailto:mdyer@endocrine.org).

## **Clinical News**

### **Endocrine Society to Launch CPG Mobile App at ENDO 2016**

The Endocrine Society will launch a new Clinical Practice Guidelines app at ENDO2016. The app offers healthcare providers access to Endocrine Society guidelines and educational resources. The free, interactive app provides point-of-care to evidence-based clinical guideline content, interactive tools (calculators, risk scores, algorithms), articles, webinars, and other educational resources for endocrinologists, primary care physicians, and other healthcare professionals caring for patients with endocrine disorders. The app currently includes the following six clinical practice guidelines:

- Diabetes and Pregnancy
- Endocrine and Nutritional Management of the Post-Bariatric Surgery Patient
- Evaluation and Management of Adult Hypoglycemic Disorders
- Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting
- Pharmacological Management of Obesity
- Primary prevention of Cardiovascular and Type 2 Diabetes in Patients at Metabolic Risk

Upcoming guidelines on diabetes technology and pediatric obesity will be added later this year.

The app can be downloaded starting Monday, April 1<sup>st</sup> from the Apple Store or Google Play by searching "Endocrine Society CP Guidelines." Please visit the [Endocrine Society's website](#) for additional information.

### **Part B Drug Payment Demonstration Project Proposed by CMS**

In an effort to rein in the increasing cost of prescription drugs and improve quality of care, the Centers for Medicare and Medicaid Services (CMS) has announced a [5-year demonstration project](#) focused on Medicare payments for Part B drugs. The demo will include all physicians billing Medicare for Part B drugs, dividing them into two groups based on zip code initially –

- Group 1 will continue to be paid under the current formula for Part B drugs based on the average sale price (ASP) plus 6 percent.
- Group 2 will be paid for these drugs based on ASP plus 2.5 percent plus a flat fee payment of \$16.80 per drug per day.

Phase I of the demo project will be implemented "60 days after the finalization of the rule," which is expected to be in Fall 2016. The Phase I proposed rule excludes drugs infused with a covered durable medical equipment, including insulin pumps.

Phase II will focus on the use of value-based tools in conjunction with the Phase I variation of the ASP add-on payment amount. Although the tools that will ultimately be used have not been determined, CMS has stated that it will consider reference pricing, discounting or rebates, pricing based on safety and cost-effectiveness for different outcomes, and outcomes-based risk-sharing agreements, among others. Phase II will begin no earlier than January 1, 2017.

The Endocrine Society is currently reviewing the rule and the potential impact on endocrinologists and their patients. This demo project may benefit patients by lowering or eliminating cost-sharing, and according to the CMS impact assessment, endocrinologists are expected to be minimally impacted by the changes. Key issues are whether the demonstration will reduce patients' access to appropriate therapies and how it will impact physician payment. Additional details and analysis will be provided in future editions of *Endocrine Insider*.

## **Research News**

### **Congress Holds Hearing on Research Funding; NIH Director Highlights Endocrine Society Advocacy Priorities**

On Wednesday, March 16, the Director of the National Institutes of Health (NIH), Francis Collins, MD, testified during a hearing of the House Appropriations Subcommittee on Labor, Health and Human Services (LHHS) on the NIH fiscal year (FY) 2017 budget request. Dr. Collins highlighted specific Endocrine Society priorities during questions.

LHHS Chairman Tom Cole (R-OK) expressed pride in being able to increase NIH funding by \$2 billion in FY 2016. He reinforced the need to ensure that the basic biomedical research base is sustained in future years through the appropriations process and remarked on the importance of supporting the next generation of researchers towards finding future cures. However, Chairman Cole was disappointed that the President's budget proposed a cut to the NIH appropriation of \$1

billion in FY 2017. He also maintained that funding outside of the appropriations process, such as mandatory funding streams, would not be an appropriate path to sustained NIH funding.

In response to a question from Chairman Cole about what the NIH could do with additional funds beyond the President's Budget Request, Dr. Collins indicated that they would like to support more investigator-initiated research. He indicated that scientists across the country deliver great ideas to the NIH and that raising the success rate for investigator-initiated grants would have positive impacts "across the board". Increasing support for investigator-initiated research has been a major priority of the Society.

In addition, Dr. Collins mentioned ten areas where he expects to see "major progress" over the coming decade with sustained funding for the NIH. One of the key predictions by Dr. Collins was the "introduction of a safe and effective artificial pancreas" for patients with diabetes, another priority of the Society.

During questions by members of the Subcommittee, Congresswoman Rosa DeLauro (D-CT) brought up the new NIH policy to require applicants to report plans to include males and females in preclinical research studies and stressed that this was an important issue for her and Congresswoman Nita Lowey (D-NY). Dr. Collins confirmed that the focus on male animals and cells in research has resulted in researchers missing important sex differences that might be critical for human treatments and cures and discussed the implementation of the new NIH policy.

The Endocrine Society is encouraged that the Director's comments, and the questions from Members of Congress reflected the advocacy priorities of Society members. We have long supported the adoption of artificial pancreas technology through our advocacy program, and we are glad that Dr. Collins recognizes the potential of this groundbreaking technology on the lives of patients. The Endocrine Society also advocates for steady increases in funding that would allow the NIH grant success rate to return to a more sustainable level. Finally, the Endocrine Society has been a leader in advocating for balancing the study of males and females in all phases of biomedical research. The Endocrine Society will continue to advocate on behalf of Society members to the NIH and Members of Congress. Please watch for a new NIH funding campaign to launch during ENDO.

## **Senate HELP Committee Introduces New Medical Innovations Bill; Considers Major Changes to Current NIH Travel Policy**

As mentioned previously in [Endocrine Insider](#), The Senate Health, Education, Labor and Pensions (HELP) Committee has begun discussions on legislation that will be combined to form the Senate's Medical Innovations bill. The Innovations bill will be the Senate's version of the House-passed [21st Century Cures \(HR 6\) legislation](#) and aims to enhance research at the National Institutes of Health, improve the approval process of new drugs and devices at the Food and Drug Administration, and address concerns of the medical community on electronic health systems.

On March 17, Chairman Lamar Alexander (R-TN) and Ranking Member Patty Murry (D-WA) introduced the FDA and NIH Workforce Authorities Modernization Act. The legislation seeks to increase coordination between the agencies and remove “red tape” that stands in the way of hiring top researchers, doctors, and staff. The goals of the bill, as articulated in the press release, are to:

- Help attract outstanding young researchers and scientists to FDA
- Allow FDA to compete with the private sector for top performers
- Help FDA better share knowledge and research between its three centers
- Encourage FDA and NIH scientists to keep up with newest developments
- Help FDA regulators keep up with the most recent scientific advancements to improve its regulatory process
- Keep unhelpful paperwork requirements from slowing down important research at the NIH

Importantly, the bill contains language that would exempt scientific meetings attended by scientific or medical personnel from onerous travel restrictions imposed on federally funded scientists and clinicians. The Endocrine Society has long argued against the excessive restrictions on government employees for travel to scientific conferences such as ENDO. The Society will closely monitor the FDA and NIH Workforce Authorities Modernization Act and the other bills being brought up during the Medical Innovations meetings. This bill, along with other yet-to-be-released pieces of legislation, will be further debated on April 6.

## **Meet & Learn from NIH & HHS Experts at the 2016 NIH Regional Seminars**

The NIH Office of Extramural Research will be offering two NIH Regional Seminars on Program Funding and Grants Administration in 2016. These 2-day seminars, with optional workshop days, are taking place in [Baltimore, MD](#) (May 11-13) and [Chicago, IL](#) (Oct. 26-28). The program is geared towards new investigators and extramural research administrators wanting to learn more about the NIH grants application and award processes. These seminars offer a unique opportunity for attendees to interact with over 60 NIH & HHS program, review, grants and policy officials in a central location, who are eager to share their expertise and answer your questions. There are over 45 different topics to choose from over the course of the 2-day seminar, plus more in-depth opportunities during our optional pre-seminar workshop day on topics such as Human Subjects Research Protections (CME Accredited Course), Intellectual Property, and electronic Research Administration. To find out more, check out the specific location links above or the [NIH Regional Seminars on Program Funding and Grants Administration](#) home page, which includes Listserv information.

## **Nomination Deadline for PCORI Advisory Panel Extended**

Recently, the Patient Centered Outcomes Research Institute (PCORI) announced that applications for 7 Advisory Panels will continue to be accepted through Thursday, March 31 at 5:00 PM ET. PCORI Advisory Panels provide advice and issue recommendations to the institute that is considered by PCORI staff. The insights of Advisory Panels are taken into consideration in patient and stakeholder engagement efforts; refining and prioritizing specific research questions; providing scientific and technical expertise; and other relevant questions that may arise.

For the 2016 selection cycle, PCORI seeks applications for the following Advisory Panels:

- Advisory Panel on Assessment of Prevention, Diagnosis, and Treatment Options
- Advisory Panel on Improving Healthcare Systems
- Advisory Panel on Addressing Disparities
- Advisory Panel on Patient Engagement
- Advisory Panel on Clinical Trials
- Advisory Panel on Rare Disease



- Advisory Panel on Communication and Dissemination Research

PCORI Advisory Panels must include “practicing and research clinicians, patients, and experts in scientific and health services research, health services delivery, and evidence-based medicine who have experience in the relevant topic, and, as appropriate, experts in integrative health and primary prevention strategies.”

**Take Action:** We encourage interested members of the Endocrine Society with appropriate expertise in the above subject areas to submit an application to serve on a panel. Applicants for a panel must fill out an online application form with a series of multiple choice and open-form questions, in addition to a personal statement of 250-500 words. For more information and instructions, please see the PCORI website here: [PCORI Application Process](#).

## Media Relations Update

### **CNN Covers Research Published in *JCEM* on Economic Costs of Women's Reproductive Disorders Linked to EDC Exposure**

On March 22, CNN.com featured research by Endocrine Society member Dr. Leo Trasande on the economic costs of women’s reproductive disorders linked to EDC exposure. The Society distributed a [release](#) on the study, which was published in [JCEM](#).

You can read the CNN.com coverage [here](#). The story is also being picked up by a number of local television outlets that receive syndicated news from CNN.

For questions regarding articles listed in *Endocrine Insider* or information on advocacy and policy activities or media relations within the Endocrine Society, contact:

Mila Becker, Chief Policy Officer, Advocacy & Policy Programs  
202-971-3633  
[Mbecker@endocrine.org](mailto:Mbecker@endocrine.org)

Stephanie Kutler, Director, Quality Improvement  
202-971-3635  
[Skutler@endocrine.org](mailto:Skutler@endocrine.org)

Aaron Lohr, Director, Media Relations  
202-971-3654  
[Alohr@endocrine.org](mailto:Alohr@endocrine.org)

Meredith Dyer, Associate Director, Health Policy  
202-971-3637  
[Mdyer@endocrine.org](mailto:Mdyer@endocrine.org)

Jenni G. Gingery, Associate Director, Media Relations  
202-971-3655  
[Jgingery@endocrine.org](mailto:Jgingery@endocrine.org)

Joseph Laakso, PhD, Associate Director, Science Policy  
202-971-3632  
[Jlaakso@endocrine.org](mailto:Jlaakso@endocrine.org)

Linda Wilkins, Manager, Clinical Affairs  
202-971-3698  
[Lwilkins@endocrine.org](mailto:Lwilkins@endocrine.org)

Jessica Nelson, Specialist, Government and Public Affairs  
202-971-3660  
[Jnelson@endocrine.org](mailto:Jnelson@endocrine.org)