



August 31, 2017

Advocacy News

Endocrine Society Partners with ADA, JDRF to Respond to Hurricane Harvey

The Endocrine Society has partnered with the American Diabetes Association and JDRF to respond to needs of people affected by Hurricane Harvey. Our organizations are working to provide needed supplies, coordinate donations and communication, and get information and help to providers, researchers, and trainees.

We have heard from some of our members who are safe and waiting out the storm; we also know there are others who have been evacuated, rescued from their homes, and whose facilities are closed due to catastrophic damage. Below are links to resources and information about what some drug companies are doing to reach patients in need. We will post additional information on our website www.endocrine.org as our work progresses. In the meantime, **we particularly would like to hear from members if there is anything the Society can do to help clinicians and researchers with their lifesaving work. Please contact info@endocrine.org.**

Information and resources include:

- [How to donate diabetes supplies to Insulin for Life](#)
- [Live map of open shelters](#) from the American Red Cross, or 1-800-733-2767
- [Federal Emergency Management Agency \(FEMA\)](#) and [federal aid programs](#) for Texas residents
- [Department of HHS](#) support services, HHS Disaster Distress Line 1-800-985-5990
- The [Centers for Disease Control and Prevention \(CDC\)](#) hurricane resources

- Link to [list of open pharmacies](#) in the Houston area
- Texas Health and Human Services – call 211 for assistance
- The [Partnership for Inclusive Disaster Strategies](#) has a hotline, 1-800-626-4949, to help people with disabilities and the elderly to safety and provide immediate needs of durable medical equipment and supplies
- [Americares](#) is providing emergency support and services
- List of [Texas food banks](#)
- [South Texas Blood and Tissue Center](#) – to find a South Texas location to donate blood, call 210-731-5590
- American Red Cross – for [nationwide locations to donate blood or platelets](#)

Eli Lilly and Company has provided an update on their efforts via [social media](#) and a [blog post](#), which include working with Direct Relief International (DRI) to deliver insulin (and other medications) locally and helping to identify [pharmacies](#) that are open to serve patients.

Insulet is reaching out to patients and providers through [social media](#) and is responding to needs and inquiries through its customer care team, which can be reached at 800-591-3455. Their local contacts will also have additional supplies to distribute as needs are identified.

Novo Nordisk has announced, via their [blog post](#), their partnership with AmeriCares for product donations (including their medicines) to non-profit organizations. Inquiries from non-profit organizations should be directed to AmeriCares via 800-486-Help.

Sanofi encourages patients to reach out to the Hurricane Harvey emergency response departments of their NGO partners Direct Relief (805-879-4902) and Americares (203-658-9500).

Budget and Appropriations Battle at Center Stage; Take Action TODAY to Urge Congress to Increase NIH Funding

When Congress returns to DC following Labor Day, it has only 12 working days to come to agreement on appropriations bills, a deal to raise the debt limit, and a deal to increase the budget caps before the end of the fiscal year on September 30. This convergence of factors raises the

likelihood of at least a short-term continuing resolution (CR) that would keep the government running while legislators finalized spending bills for the next fiscal year. However, the likelihood of a government shutdown increases daily.

Currently, the House of Representatives has proposed a legislative package that includes all the remaining spending bills that have yet to be passed (known as the “omnibus spending bill”), including the bill for Labor, Health and Human Services, which funds the NIH; a vote on the omnibus is anticipated in early September. However, the total discretionary spending for the omnibus would violate the budget caps imposed by the Budget Control Act, immediately triggering cuts known as “sequestration”, absent a broad budget deal that raises the caps. Moreover, the Senate has yet to propose spending bills, and President Trump has threatened to veto any spending bill that does not include funding for a border wall.

Take Action: The Society has visited Congress, submitted testimony, called on the House and Senate to increase NIH funding, and will be a sponsor of a Rally for Medical Research in September bringing hundreds of research and patient advocates to Capitol Hill. But, given the uncertainty and conflicting priorities of various factions in the Congress, we need all our members to add their voices so that the Congress appreciates that a shutdown or long-term continuing resolution would hurt biomedical research and prevent our members from conducting lifesaving research. To join your colleagues and make a difference, we have implemented a special advocacy campaign on the Society’s [advocacy webpage](#). Please take 1 minute of your time to complete the online campaign and send a letter to your representative and Senators. (Our software will provide a draft letter and direct it to your Representative and Senators for you.) Only a robust response from the research community will ensure that Congress provides the NIH with the funds that the biomedical research enterprise desperately needs.

Society Working with Congress to Address Insulin Price Increases & Implications of Non-Medical Switching; Share Your Feedback with Us

The Endocrine Society is working with Members of Congress to address rising drug costs and non-medical switching on patient care. As you know, the cost of insulin has nearly tripled since 2002. Patients are increasingly being exposed to these costs because of high deductibles and coinsurance. Shifting formulary placements have forced patients to switch medications from year to year. And, physicians must navigate each of these barriers to successfully treat and improve the health of their patients.

We want to better understand these barriers so we can communicate them back to Congress and influence new policy. We want to hear from you about your experience.

We are seeking feedback on the following questions:

- What do you take into consideration when making prescribing decisions for patients on insulin. How do you determine which product might work best for a particular patient?
- Do health plans provide information on how an insulin product is covered and is it available at the time of prescribing? Do you have a general sense of what the insulin product will cost before prescribing it?
- Do you recommend patient assistance programs or discount coupons to patients as a way to reduce out-of-pocket costs? How accessible are these programs for your patients? Are there specific ways these programs can be more accessible?
- Does marketing or communications from insulin manufacturers impact your prescribing decisions?
- What factors do you take into account when switching a patient from one insulin to another? Is this a common occurrence? Are costs a common reason for switching insulins?
- Given non-medical switching is likely to continue, how would you improve this process? What information do plans need to know? What information would you like to have? What information would a patient benefit from?

Please respond to Meredith Dyer at mdyer@endocrine.org by September 20th with your feedback so we can include in our formal response and recommendations to Congress.

Clinical News

Society QPP Comments Focus on Issues of Importance to Endocrinology; Session at CEU Will Provide More Information

As reported in the June issue of [Endocrine Insider](#), The Centers for Medicare and Medicaid (CMS) released its [proposal for the second year of the Quality Payment Program \(QPP\)](#). The proposed rule carries over many of the requirements from the 2017 reporting year, and makes changes that aim to reduce the reporting burden and allow clinicians to spend more time with their patients.

We were pleased with a number of changes that CMS proposed, particularly those that support smaller practices and provide for another transition year to allow providers to ease into the new

program. The proposed rule included two changes that will directly impact endocrinologists – a complex patient bonus and two new Improvement Activities (IAs) focused on Type 2 diabetes.

CMS has proposed the creation of a complex patient bonus to add to the final Merit-based Incentive Payment System (MIPS) score for the 2020 MIPS payment year for clinicians that submit data for at least one performance category. The bonus would be calculated by finding an average Hierarchical Condition Category (HCC) risk score for each MIPS eligible clinician or group. The Society supports the proposal to create a complex patient bonus as many of the patients that endocrinologists treat have complex diseases. However, we are concerned with the proposed usage of the HCC risk score as the basis for calculating the complex patient bonus. In the Society's [comments](#), we urged CMS to thoroughly study the appropriateness of using HCC risk scores to calculate the complex patient bonus.

The proposed rule also includes two new IAs that focus on screening and preventing Type 2 diabetes. We are pleased that CMS has included IAs to recognize the efforts of clinicians to identify patients at risk of developing Type 2 diabetes and preventing the progression through referral to a Diabetes Prevention Program (DPP). However, we [expressed concern](#) that the proposed reporting threshold for both activities will be unattainable by most clinicians and will discourage clinicians from selecting these to fulfill the IA requirement. This will have an adverse impact on the diabetes community's efforts to spur greater activity in screening and referring eligible patients to DPP programs. We asked that CMS lower the thresholds for both IAs for the first year.

The final rule will establish the structure of the QPP for 2018 and is expected to be released later this Fall. In the interim, **the Society will be hosting a session at [Clinical Endocrinology Update \(CEU\)](#) to share more specifics on the proposed changes and answer members' questions about the QPP. Please join us on Monday, September 25th at 7 am to learn more about how these changes could impact your practice.**

Society Shares Concerns about Competitive Bidding Program with HHS Secretary Price

The Endocrine Society submitted [comments](#) to HHS Secretary Tom Price citing concerns with the Competitive Bidding Program (CBP) and its impact on patient access to diabetes devices and supplies. The letter discusses new findings that the CBP provides blood glucose monitors that fail to meet FDA standards in its mail order program and asks the Secretary to reevaluate the effectiveness of the program. The Society also urges HHS to enforce existing FDA standards for

safety and quality in determining which supplies are included in the CBP. We will continue to work with HHS to address access issues for patients with diabetes and will inform our members if changes to the program result from these efforts.

FDA Announces Cardiovascular Risk Reduction Indication for Liraglutide

The U.S. Food and Drug Administration confirmed a new indication for liraglutide (Victoza) following a FDA advisory panel approval last June. The new indication states that liraglutide reduces the risk of major adverse cardiovascular events in adults with Type 2 Diabetes; it is only the second diabetes drug, after empagliflozin, to receive this indication. This approval follows evidence from the LEADER trial that found a 13% reduction in the risk of a composite of cardiovascular death, non-fatal heart attack, and non-fatal stroke. The Society provided [testimony](#) at the FDA advisory panel supporting expanded availability of therapies for patients with diabetes. Several cardiovascular outcomes trial results have demonstrated similar reductions in adverse events. We will provide additional testimony to the FDA as new indications for these drugs are considered.

Research News

NIH Continues to Implement New Clinical Trial Policies

The National Institutes of Health is taking steps to implement revisions to their definition of a clinical trial, or “a research study in which one or more human subjects are prospectively assigned to one or more interventions on health-related biomedical or behavioral outcomes.” Although this definition was published in 2014, subsequent guidance suggests that the definition will incorporate more studies previously not considered clinical trials.

The NIH, in an [Open Mike blog post](#), further illustrated the policy by posing four questions:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

If the answer to all these questions is “yes”, then the study is considered a clinical trial by the NIH. Such studies would be subject to additional requirements, such as registration on clinicaltrials.gov.

We encourage members of the Endocrine Society to carefully examine the clinical trials requirements for grants and contracts on the [NIH website](http://nih.gov). Case studies to further assist researchers in determining if their study qualifies as a clinical trial can also be found here: <https://grants.nih.gov/policy/clinical-trials/case-studies.htm>.

For questions regarding articles listed in *Endocrine Insider* or information on advocacy and policy activities within the Endocrine Society, contact the Government & Public Affairs department:

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