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Political Action Committee Chair Report for BQSIMB 2016 Spring Meeting

1. 114th Congress (2015 - 2016) 2nd Session - S.2678

1.1 Latest Title: Safe Treatments and Opportunities to Prevent Pain Act

***Sponsor*: Sen Schatz, Brian [HI] (introduced 3/15/2016) Cosponsors (5)**
***Latest Major Action*: 3/15/2016 Referred to Senate Committee.**
***Status*: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.**

S.2678 -- STOP Pain Act (Introduced in Senate - IS) -- S 2678 IS
To direct the NIH to intensify and coordinate fundamental, translational, and clinical research with respect to the understanding of pain, the discovery and development of therapies for chronic pain, and the development of alternatives to opioids for effective pain treatments.

SECTION 1. SHORT TITLE.
This Act may be cited as the `Safe Treatments and Opportunities to Prevent Pain Act' or the `STOP Pain Act'.

SECTION 2. ENHANCING BASIC AND APPLIED RESEARCH ON PAIN TO DISCOVER THERAPIES, INCLUDING ALTERNATIVES TO OPIOIDS, FOR EFFECTIVE PAIN MANAGEMENT.
(a) In General- The Director of the National Institutes of Health (referred to in this section as the `NIH') may intensify and coordinate fundamental, translational, and clinical research of the NIH with respect to--
(1) the understanding of pain;
(2) the discovery and development of therapies for chronic pain; and
(3) the development of alternatives to opioids for effective pain treatments.
(b) Priority and Direction- The prioritization and direction of the federally funded portfolio of pain research studies shall consider recommendations made by the Interagency Pain Research Coordinating Committee in concert with the Pain Management Best Practices Inter-Agency Task Force, and in accordance with the National Pain Strategy, the Federal Pain Research Strategy, and the NIH-Wide Strategic Plan for Fiscal Years 2016-2020, the latter which calls for the relative burdens of individual diseases and medical disorders to be regarded as crucial considerations in balancing the priorities of the Federal research portfolio.

2. Update from the Association of American Medical Colleges (AAMC):

2.1 AAMC Leads Letter to CMS Calling for Delay in Star Ratings

March 25, 2016—The AAMC March 18 submitted a joint hospital association letter PDF to the Centers for Medicare and Medicaid Services (CMS) calling for a delay and modifications to the

planned release of the Hospital Compare star ratings in April 2016. The American Hospital Association, America's Essential Hospitals, and the Federation of American Hospitals also signed the letter.

Under the CMS methodology, hospitals would receive a single, overall star rating based on performance on a selection of quality measures on the Hospital Compare website. The lowest performing institutions would receive one star and the highest would receive five stars.

In the joint letter, the associations note their support for public reporting of performance data while citing concerns with the star ratings methodology and process for reporting this data. The letter states that hospitals and stakeholders had not received the full data from CMS and were therefore unable to evaluate or replicate the agency's work. Other concerns focus on appropriate risk adjustment for specific quality measures that were included in the methodology.

The associations specifically recommend the star ratings be delayed to allow for CMS to better understand the impact of the ratings and to determine whether any category of hospitals are disproportionately disadvantaged by the methodology. Additional recommendations include sharing the complete data with hospitals and stakeholders, a sociodemographic status adjustment for accountability measures used in the methodology, and the removal of certain quality measures that have been previously identified as insufficiently risk adjusted, such as the PSI-90 composite measure.

2.2 CMS Releases Interactive Tool to Map Health Disparities Among Medicare Beneficiaries

March 25, 2016—The Centers for Medicare and Medicaid Services (CMS) unveiled a new tool that maps geographic disparities in chronic diseases among Medicare beneficiaries. The Mapping Medicare Disparities tool displays geographic differences in health care outcome, utilization, and cost – including measures such as disease prevalence, Medicare spending, hospital and emergency department utilization, preventable hospitalizations, readmission rates, and mortality – for 18 chronic conditions.

CMS Acting Administrator Andy Slavitt stated, "Our commitment to health equity begins with properly measuring the care people get and having an honest dialogue on how and where we need to improve. Today's tool aims to make it harder for disparities to go unaddressed."

3. Update from the ACGME (Accreditation Council for Graduate Medical Education)

3.1 Update on Two Multicenter Trials December 7, 2015

Excerpts from the update provided by Dr. Thomas J. Nasca, CEO of ACGME in December 2015 (to see a full document, please follow the link below): http://www.acgme.org/Portals/0/PDFs/NascaLetterCommunityDutyHoursMulticenterTrialsUpdateDec2015.pdf).

Dr. Nasca updated nation-wide GME community on his previous letter from March 2014 (as reported first at our Spring 2014 Meeting) announcing the *ACGME's support of two large, multicenter clinical trials investigating the impact of duty hour standards on patient safety and resident education*.

The ACGME's current duty hour accreditation requirements were developed in 2011 based on the best available evidence at the time. These requirements are based on the findings and recommendations of the *2010 ACGME Task Force on Quality Care and Professionalism*, which conducted a thorough investigation of published evidence on duty hours and sleep science,

heard testimony from experts and patients, and was informed by the 2009 Institute of Medicine (IOM) report, *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*.

Since the 2009 IOM report and the implementation of the new ACGME duty hour requirements, a number of studies have been conducted to assess the impact of the additional standards instituted in 2011. *The preponderance of this new published research suggests that the additional 2011 duty hour requirements may not have had an incremental benefit in patient safety, and that there might be significant negative impacts to the quality of physician education, professional development, and socialization to the practice of medicine.*

To further investigate these issues, *the ACGME provided seed funding and agreed to waive specific duty hour requirements for two national large, independent, multicenter trials.* The ACGME granted these waivers to allow for the collection of data evaluating the impact of the 2011 duty hour requirements on patient safety along with the welfare and education of resident physicians.

The iCOMPARE trial for internal medicine and the FIRST trial for general surgery were designed so that researchers can compare control groups using the current requirements with test groups following more flexible duty hour requirements. The waivers were granted for the length of each research trial (June 2016 for the completion of the FIRST trial, and July 2017 for the completion of the iCOMPARE trial).

The ACGME did NOT waive the central requirements for duty hours that have been in place since 2003 for all specialties, and for internal medicine since the early 1990s. The requirements limiting the total number of hours per week remain in effect for all trial participants (i.e., 80 hours per week—averaged over four weeks; one day off in seven averaged over four weeks; and 24-hour in-house call duty no more frequently than every third night). *Compliance with these requirements is monitored annually in the Next Accreditation System for all programs across all specialties, including those participating in these two trials.*

In addition, all first year (PGY-1) residents are required to have real-time, on-site, direct supervision in which a more experienced clinician bears the responsibility for patient care. The un-waived requirements also allow fatigued residents to hand off patients at any time, recommend napping after 16 hours of duty, and provide adequate sleep facilities and/or safe transportation options for residents who may be too fatigued to safely return home.

The ACGME was not involved in the design or implementation of the FIRST or the iCOMPARE trials beyond the waiver requirements, and will not be involved in the interpretation of their results. Nevertheless, the *ACGME understands that both duty hour study protocols were reviewed by the Institutional Review Board (IRB) of the institution affiliated with each principal investigator*. The *ACGME also understands that the iCOMPARE trial was funded by the National Institutes of Health (NIH)*.

Respectfully submitted via email on March 29, 2016 by Rimma Perelman, Chair of Political Action Committee, BQSIMB.