US H.R.6 of the 115th Congress of the United States 2017-2018 Session

This Act may be cited as the "Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act" or the "Support for Patients and Communities Act".

Thanks to Kallie Guimond, IHPC Director of Government Affairs | IHPC Review of Legislative Action | October 19, 2018
for the preliminary review and summary.
This narrative overview provided further by David W. Miller, American Society of Acupuncturists, October 28, 2018

https://www.congress.gov/bill/115th-congress/house-bill/6/text

Introduction

HR 6 is bipartisan legislation signed into law on October 24, 2018. It is intended to address the role of Medicare and Medicaid (under the Social Security Act) in improving services that can mitigate opioid overuse and abuse. Its highlights for the integrative health community center around language that explicitly includes and mandates the study of non-pharmacologic approaches to pain control. **This legislation is the first in U.S. history to specifically name "acupuncture" and "therapeutic massage" in public documents.**

It is critical to understand that this legislation contains no mandates of coverage nor endorsements of specific non-pharmacological approaches to pain management. It does not in any way include these modalities or others yet into Medicare and Medicaid services. This legislation is first and foremost about a mandate for study and the creation of reports covering what is currently being done for pain management and what could be done better. The end result of this legislation is not implementation of new therapies, but rather the creation of at least one guidance document to direct the Centers for Medicare and Medicaid Services (CMS) on how to modify its current offerings to better include evidence based treatment for acute and chronic pain, using both pharmacologic and non-pharmacologic (hereafter "pharm and non-pharm") strategies, with the end goal being a reduction in use of and harms caused by opioids. It does provide for significant grant funding to hospitals and free-standing emergency departments for related study, and mandates the creation of educational documents.

This legislation has a number of very significant provisions for the pain management community, and is exceptional in that it mandates inclusion of numerous groups in the creation of its reports. Groups included are noted below, but expand beyond solely an internal process to gather input from all types of healthcare professionals, patient advocacy groups, professional medical associations working to manage pain, and patients themselves. This legislation provides the opportunity for the integrative medicine community and for the patients who have benefitted from integrative care to "step up and speak up"! There will be calls for input,

information, evidence, and testimony. Those with an interest in seeing the inclusion of integrative, non-pharm care must act when called upon. If the windows are missed, the opportunity is lost.

Further, it is absolutely critical that all players in the integrative field coordinate care and messaging. More input is not nearly so valuable as high-quality input from trusted sources. Our professional organizations must work together to rapidly create consensus documents, and submit these with unified endorsement. This strategy will most constructively influence this process, and improve chances for inclusion of non-pharm strategies in the outcome guidance document(s). Not every type of therapy will or can be included. Only therapies with a strong evidence base will be considered. Each step outlined in the legislation provides an opportunity for participation.

Summary of Relevant Sections

Section 6021. MEDICARE OPIOID SAFETY EDUCATION.

Resource Compilation
The relevant governmental departments (Health and Human Services and CMS predominantly) will be collecting and compiling lists of educational resources regarding opioid use and pain management in general. They will also be reviewing the current system, and creating a list of currently covered categories of “alternative, non-opioid pain management treatments” (including both pharm and non-pharm).

Mandated Recommendation to “Speak to a Physician”
Beginning January 1, 2019 and at the start of every enrollment period thereafter, Medicare and Medicaid recipients will receive a mandated suggestion to talk to a physician about opioid use and alternative options. They will receive a list of resources available to them, likely both for general education and for alternative treatments. There is no specific content inclusion in the legislation as to what a physician shall say to the beneficiary, so the determination of best practices in this remains to be determined. This is an opportunity for the integrative health community to influence this dialog.

Section 6032. ACTION PLAN ON RECOMMENDATIONS FOR CHANGES UNDER MEDICARE AND MEDICAID TO PREVENT OPIOIDS ADDICTIONS AND ENHANCE ACCESS TO MEDICATION-ASSISTED TREATMENT.

Identification of Obstacles
The “Pain Management Best Practices Inter-Agency Task Force”[1] was created back in 2016 and is made up of many types of participants including: representatives of pain management professional organizations, the mental health treatment community, the addiction treatment community (including individuals in recovery from substance use disorder), pain advocacy

[1] https://www.gpo.gov/fdsys/pkg/PLAW-114publ198/pdf/PLAW-114publ198.pdf

groups (including patients), and veteran service organizations. By Jan 1, 2020, this Task force will work with the Secretary of Health and Human Services (HHS) to develop an action plan that includes a review of current payment and coverage policies that may be viewed as potential obstacles to an effective response to the opioid crisis.

Self-Assessment

CMS will look at the costs currently associated with the prevention and treatment of opioid overuse and addiction under current Medicare and Medicaid through FDA approved methods, and also review the current status of coverage and payment. They will also look beyond the FDA approved methods to other therapies that manage chronic and acute pain and treat and minimize risk of opioid misuse and abuse. An analysis will be performed to determine if the policies, procedures, and payment schema currently in place seems to be helping to solve problems related to the opioid crisis, or if they are exacerbating problems.

Involvement

Stakeholder meetings will be held in the near future. Participation is wide, and includes health care providers. By the beginning of 2020, the mandated report will be completed. Relevant stakeholders should act now to have their input included. The call for input by the government must be made prior to January 24, 2019.

Safeguards

Provisions will be put into place to assure there are no inherent, unintended financial incentives that would encourage opioid use over other options.

Future thinking

HHS and the Pain Task Force will make recommendations for payment and service delivery models to be tested by "the Center for Medicare and Medicaid Innovation" and other federally authorized demonstration projects, including value-based models, that may encourage the use of pharm and non-pharm therapies that manage chronic and acute pain and treat and minimize risk of opioid misuse and abuse. They will be looking for any useful data relative to this effort.

A review of Medicare and Medicaid beneficiaries' access to the full range of pharm and non-pharm therapies that manage chronic and acute pain and treat and minimize risk of opioid misuse and abuse, including access for beneficiaries residing in rural or medically underserved communities will also be conducted.

Section 6084. STUDYING THE AVAILABILITY OF SUPPLEMENTAL BENEFITS DESIGNED TO TREAT OR PREVENT SUBSTANCE USE DISORDERS UNDER MEDICARE ADVANTAGE PLANS.

By October 24, 2020, HHS will need to submit an additional report reflecting an analysis of the extent to which current plans (Medicare and Medicaid) offer health care benefits relating to the coverage of non-opioid alternatives for the treatment of pain. This report shall cover the challenges in offering those alternatives, how those would affect costs, and potential ways to

improve upon such coverage or to incentivize such plans to offer additional supplemental health care benefits relating to such coverage.

Information to be considered in this report will include the "VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain" published in February 2017 by the Department of Veterans Affairs and Department of Defense, including adoption of elements of the Department of Defense and Department of Veterans Affairs pain rating scale.

Section 6086. DR. TODD GRAHAM PAIN MANAGEMENT STUDY.

This section mandates a study analyzing best practices as well as payment and coverage for pain management services. This will be submitted to the Committee on Ways and Means as well as the Committee on Energy and Commerce (House) and the Committee on Finance (Senate). A report back with options for revising the current payment system, esp. related to multi-disciplinary, evidence-based, non-opioid treatments for acute and chronic pain management for individuals covered under Medicare and Medicaid is mandated. This report will be publicly available on the CMS website.

Consultants for this report shall include licensed and practicing osteopathic and allopathic physicians, behavioral health practitioners, physician assistants, nurse practitioners, dentists, pharmacists, and other providers of health services; pain management professional organizations and advocacy entities, including individuals who personally suffer chronic pain; medical professional organizations and medical specialty organizations, licensed health care providers who furnish alternative pain management services.

The report will include information on treatments both currently covered and those not covered. It will also include information on barriers to access, cost-benefit ratios, and "information on practices such as acupuncture (Section 6086 C2B), therapeutic massage, and items and services furnished by integrated pain management programs."

Select Goals

- Improve coverage of and payment for pain management therapies without the use of opioids, including interventional pain therapies, and options to augment opioid therapy with other clinical and complementary, integrative health services to minimize the risk of substance use disorder, including in a hospital setting.

- Improve coverage of and payment for medical devices and non-opioid based pharmacological and non-pharmacological therapies approved or cleared by the Food and Drug Administration for the treatment of pain as an alternative or augment to opioid therapy.

- Expand outreach activities designed to educate providers of services and suppliers under the Medicare program and individuals entitled to benefits on alternative, non-opioid therapies to manage and treat acute and chronic pain.

- Create a beneficiary education tool on alternatives to opioids for chronic pain management.

Other Agencies and Areas

Section 6092. DEVELOPING GUIDANCE ON PAIN MANAGEMENT AND OPIOID USE DISORDER PREVENTION FOR HOSPITALS RECEIVING PAYMENT UNDER PART A OF THE MEDICARE PROGRAM.

Provides guidance for hospitals on non-opioid (pharm and non-pharm) recommended best practices.

SEC. 6102. REQUIRING MEDICARE ADVANTAGE PLANS AND PART D PRESCRIPTION DRUG PLANS TO INCLUDE INFORMATION ON RISKS ASSOCIATED WITH OPIOIDS AND COVERAGE OF NONPHARMACOLOGICAL THERAPIES AND NONOPIOID MEDICATIONS OR DEVICES USED TO TREAT PAIN.

Mandates that Medicare Advantage plans and Part D prescription drug plans educate on pharm and non-pharm options for opioids, as well as on the dangers associated with opioid use.

Section 7042. PAIN RESEARCH.

Guides current and future research on pain, including coordination with the NIH (7042 C, i, ii, iii) on research efforts for pharm and non-pharm pain approaches.

SEC. 7091. EMERGENCY DEPARTMENT ALTERNATIVES TO OPIOIDS DEMONSTRATION PROGRAM

Provides $10,000,000 per year for 3 years in grants to hospitals and emergency departments to develop, implement, enhance, and/or study alternatives to opioids for pain management in the hospital and ED settings. Grant funds can be used to target treatment approaches for pain conditions frequently seen, to train providers and hospital personnel on protocols and best practices related the use and prescribing of opioids and pharm and non-pharm alternatives, and to develop or continue the provision of such services.

Data will be collected from these efforts and used for further guidance of program development.

Timeline

- **January 1, 2019:** HHS via CMS issues at least one guidance document or update to existing documents regarding mandatory and optional items and services that may be provided under state plans or Medicare/Medicaid for for non-opioid treatment and management of pain, including, but not limited to, evidence-based, non-opioid pharm and non-pharm therapies.

- **January 24, 2019:** Stakeholder meetings will begin to be called to help develop the action plan described in Section 6032. Also, HHS shall issue a request for information seeking public feedback regarding ways in which the Centers for Medicare & Medicaid Services can help address the opioid crisis through the development of and application of the action plan.

- **July 1, 2019:** HHS will publish its guidance document for hospitals.

- **October 24, 2019:** The analysis of the financial implications and best practices for pharm and non-pharm, non-opioid treatments for pain as outlined in Section 6086 (the Dr. Todd Graham Pain Management Study above) will be ready and submitted to the House and Senate finance committees for further evaluation.

- **January 1, 2020:** The action plan described in Section 6032 shall be completed.

- **June 1, 2020:** HHS will turn the findings of the action plan into a public report which will be submitted to Congress.

- **October 24, 2020:** HHS will submit to Congress a report on the availability of supplemental health care benefits designed to treat or prevent substance use disorders under Medicare Advantage plans. Such report shall include reference to the previous analysis and public report, and highlight any differences in the availability of such benefits under specialized MA plans for special needs individuals.

- **January – June 2022 (approximately):** HHS will submit the findings and outcomes from the grant-based explorations described in Section 7091: EMERGENCY DEPARTMENT ALTERNATIVES TO OPIOIDS DEMONSTRATION PROGRAM **.**

Conclusions

US HR6 offers robust opportunities for the integrative health community to participate in the creation of guidance documents and grant-funded studies toward the end-goal of determining how to best incorporate non-opioid, pharm and non-pharm treatments into the national pain care strategy. These documents will likely powerfully influence Medicare and Medicaid, and will directly impact the care delivered in hospitals and emergency departments nationwide. It holds the opportunity for every Medicare and Medicaid recipient to receive education on their care options for non-opioid pain control, and specifically names both acupuncture and therapeutic massage under the modalities that may be first studied for such inclusion. Well-coordinated responses from the integrative pain community are critical to accurately inform HHS and CMS of the data and possibilities toward transforming our nation's approach to the care of those suffering from acute and chronic pain. Through properly timed and collaborative action, we can take great strides toward ending the opioid crisis.

One Hundred Fifteenth Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Wednesday, the third day of January, two thousand and eighteen

An Act

To provide for opioid use disorder prevention, recovery, and treatment, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act" or the "SUPPORT for Patients and Communities Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows: