INTEGRATIVE HEALTH
POLICY CONSORTIUM

July 8, 2017

Blueprint to the Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Building, 4th Floor
Silver Spring, MD 20993-0002

Ref: Docket No. FDA–2017–D–2497 for ‘‘Draft Revisions to FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids; Request for Comments.’’

The Integrative Health Policy Consortium (IHPC) thanks the Food and Drug Administration (FDA) for the opportunity to respond to your request for public comment on your draft *Education Blueprint for Health Care Providers Involved in the Management or Support of Patients with Pain*. IHPC is a national nonprofit 501(c)(4) consortium composed of 22 organizations and institutions (“Partners for Health”) representing more than 400,000 state licensed or nationally certified healthcare professionals. Our mission is to remove barriers to health and enhance creation of health in individuals and communities. IHPC's Partner for Health organizations represent the licensed integrative and complementary professions of acupuncture, certified professional midwifery, chiropractic, holistic nursing, homeopathy, integrative medicine, massage therapy, music therapy, naturopathic medicine, and nutrition counseling.

We understand the severity of our country’s opioid crisis: loss of life, damage to families, and loss of productivity. We applaud your recommendation of non-pharmacological pain management. We are also very pleased to see your elevation of the importance of non-pharmacological and complementary/integrative approaches, similar to the 2016 CDC Guideline. However, we believe that to successfully engage healthcare providers in these significant shifts in their practices, they will require additional direction regarding the application of non-pharmacological approaches. The present document does not substantially provide guidance to practitioners in these areas. The bulk of your current document focuses on non-opioid drug interventions. Our core recommendation is that the FDA dedicate a like amount of educational power and authority to teaching practitioners how to begin making this transition to non-pharmacological approaches. In doing so, the FDA will make a significant contribution to advancing the nation toward the new approach to pain that has been recommended since the 2011 IOM Report on pain.

The IHPC offers the following specific feedback regarding the FDA's proposed Pain Management Blueprint.

The National Pain Strategy states, "*Clinicians would undertake comprehensive assessments of patients with chronic pain, leading to an integrated, patient-centered plan of coordinated care, managed by an interdisciplinary team, when needed*." Our definition of "interdisciplinary" would include (but not be limited to) the following health and wellness professionals:

- Psychologists and health coaches (To recommend coping and self-care strategies, cognitive behavioral therapy, stress management, etc.)
- Acupuncturists, chiropractors, osteopaths, massage therapists, physical and occupational therapists, naturopathic physicians, and homeopaths
- Yoga, Tai Chi and mindfulness meditation instructors

This set of practices and practitioners is similar to that listed in the Joint Commission's 2014 Pain Standard Clarification, those of greatest interest to the Department of Veterans Affairs, and those highlighted in the American College of Physicians' (ACP) Guideline on back pain. We recommend that you specifically refer to the National Pain Strategy (NPS) as well as the ACP Guideline for additional primary care practitioner guidance. Initiatives such as Project ECHO and others offer online education for providers. The Academy of Integrative Pain Management offers more than 70 educational programs on its website.

The NPS, under Disparities, Objective #1, invites as collaborators "licensed practitioners who provide integrative and complementary health approaches" in order to "reduce bias (implicit, conscious, and unconscious) and its impact on pain treatment by improving understanding ..." To adequately handle underserved communities, the FDA should recommend that Federally Qualified Health Centers (FQHC), the Indian Health Services, and other federally supported healthcare entities staff acupuncturists, massage therapists, behavioral health specialists, naturopathic physicians, homeopaths, chiropractors, nutritionists and other complementary therapy providers to offer an alternative or supplement to pharmacological treatment. Since most patients who use FQHC's typically don't have access to complementary and integrative health practitioners, the most available tool to combat pain at these facilities is opioids.

The U.S. Department of Veterans Affairs, which coordinates the care of more than 8.8 million veterans annually with more than 1,700 locations representing the largest health system in America, is a model for using integrative approaches to decrease opioid use. Complementary/Integrative care is offered in 93% of their facilities, and in 2008, 83% of soldiers treated for chronic pain at Walter Reed Army Medical center were given prescription medication (primarily opioids)and by 2011 the number of patients prescribed opioids dropped to 10.2% since the application of patient-centered integrative pain care. (Source: Killing Veterans with Pain Killers by Cameron Turner, https://www.thefix.com/content/veterans-overdose-prescription-painkillers accessed 6/25/17)

Specifically, we recommend the following additions to your draft document:

Section 2, II: General Principles of Non-pharmacological therapies

Pain can arise from a broad variety of causes. A number of non-pharmacological approaches are available that can be used to manage pain. HCPs should be knowledgeable about the range of approaches available and the types of pain that may be responsive to those approaches. These health and wellness professionals include, but are not limited to:

- Psychologists and health coaches (To recommend coping and self-care strategies, cognitive behavioral therapy, stress management, etc.)
- Acupuncturists, Chiropractors, Osteopaths, massage therapists, physical and occupational therapists and nutritionists

- Yoga, Tai Chi and mindfulness meditation instructors

We recommend a special section on self-care. This will be aligned with the NPS section, Prevention and Care, which that invites collaboration with "licensed complementary and integrative health fields" in their goal to "develop nationwide pain self-management programs..." The FDA Blueprint should advance this partnership, and this goal.

We recommend that you add a related section on practitioner and patient education on non-pharmacological and integrative practices and practitioners. This section can include basic educational resources, basic descriptions of the therapies, etc. We would be happy to direct you to appropriate resources to develop this information.

Patients can also be linked to national associations with their lists of qualified, licensed and certified practitioners.

Specifically speaking:
www.NCCAOM.org for licensed acupuncturists
http://www.medicalacupuncture.org/Find-an-Acupuncturist for medical acupuncturists
www.chiropractic.org for chiropractors
www.AMTAmassage.org for massage therapists
www.integrativepain.org for licensed professionals from multiple professions
http://ahna.enoah.com/Home/Directories/Practitioner-Directory for holistic nurses
http://www.homeopathicdirectory.com/index.html for homeopaths
https://mana.org/index.php or http://nacpm.org/find-a-cpm/ for midwives

We recommend that you add a section on payment that is aligned with the recommendation in the National Pain Strategy in Service Delivery & Payment Objective #3: "Tailor payment to promote and incentivize high-quality, coordinated pain care ..." In this section, the NPS reaches out to "licensed integrative health care providers." Some content could be:

- Provide fact sheets on the extent to which such care is covered by insurance.

- Provide patients and practitioners with basic information on who to contact in their insurance company to advocate for coverage.

Section 2, II(A): Considerations for referral to an integrative care specialist

Educate the patient about options such as acupuncture, chiropractic, massage therapy, physical therapy, cognitive behavioral therapy, homeopathy, etc. (see list in Sec 2, II) and ask which one(s) they feel most comfortable pursuing for pain relief.

Provide a list of local practitioners that the primary care practitioner could recommend; or, at a minimum, provide links to organizational websites that provide practitioner directories.

Section 2, II(B): Considerations for patient currently on opioid therapy

Similarly, to II(A), educate the patient about pain management options to transition them to non-pharmacological therapies. Jointly decide upon 2-3 SMART (Specific, Measurable, Attainable, Relevant, Time Bound) goals as measures of progress. Set goals for outcomes important to the patient, not for pain intensity, such as being able to carry their grandchild, walk a mile, or play 18 holes of golf.

Section 2, II(C): Considerations for patients addicted to/dependent on opioid medications and/or taking high doses of opioids with a desire to taper those doses

- Complementary non-pharmacological approaches for pain management should be started prior to tapering opioid doses in opioid dependent patients to provide underlying reduction in pain and reduce anxiety about controlling pain. These approaches can serve as "bridging modalities" for patients as they taper.

- Educate the patient about options for reducing post-acute withdrawal syndrome (PAWS) to include acupuncture, homeopathy, naturopathy, nutrition counseling and medical nutrition therapy, mind-body approaches, meditation, biofeedback, guided imagery, yoga, tai chi and other movement therapies.

- Educate the patient about nutritional support to address deficiencies and imbalances secondary to the addiction and to minimize risks of re-addiction

- The National Acupuncture Detoxification Association (NADA) has trained more than 10,000 healthcare professionals to treat addiction. The NADA protocol is taught to all licensed acupuncturists.

Section 2, III: Co-managing patients receiving non-pharmacological treatments

Communicate with HCPs regarding your patient's improvement from integrative approaches. HCPs should coordinate pharmacological treatment with integrative practitioner to provide seamless tapering of opioids corresponding to improvements in pain, function and quality of life.

Section 2, III(A): Initiating treatment with Integrative non-pharmacological care - acute pain

All patients should be referred to an integrative practitioner for complementary treatment. Patients may experience pain relief that will reduce their need or shorten the length of time under pharmacological care.

Section 2, III(B): Initiating treatment with Integrative non-pharmacological care - chronic pain

All patients should be referred to an integrative practitioner for complementary treatment prior to adjusting pharmacological medications in order to treat underlying cause of pain, reduce neurological hyperresponsiveness, and allay anxiety about pain control.

Section 2, III(C): Periodic review and monitoring: Patients receiving integrative care

Patient response should be reviewed after 2 weeks and periodically thereafter and monitored by functional assessments.

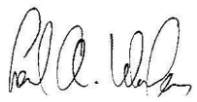
Section 2, III(D): Long-term management

All integrative practitioners involved should provide periodic progress reports to the HCP and the patient. All integrative practitioners, the HCP, and the patient should meet regularly to discuss progress and treatment plan.

The FDA Pain Management Blueprint offers a critical step forward in our country's battle with pain and opioid addiction in addition to the CDC Opioid Prescription Guidelines, the National Pain Strategy, and the American College of Physician's Low Back Pain Clinical Practice Guideline. Educating HCPs on non-pharmacological options for their patients is paramount, and following the Department of Veterans Affairs lead on patient-centered pain care will reduce opioid prescriptions and needless loss of life.

Thank you for your attention to our feedback and recommendations in response to your request for public comments on your Pain Management Blueprint. We are pleased to serve as a resource should further information be desired.

Sincerely,



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