HHS-CMS Petition for Rule Suspension and Management Review

This notification is to petition the US Centers for Medicare and Medicaid Services for immediate suspension of announced 2019 Medicare Part D rule changes pertinent to "Real-Time Care Coordination Safety Edits to Address Chronic Opioid Use," until January 2020. See Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, pp 243-253.

Due to the potential for grievous harms to pain patients and care providers from CMS rule changes, expedited processing of this petition is requested.

Grounds for this petition:

(1) As written, the proposed Medicare rule changes are explicitly intended to implement provisions of the March 2016 Centers for Disease Control guidelines on opioid prescription in chronic adult non-cancer pain. As further detailed in this petition, it is now widely known that the CDC Guidelines are fatally flawed, wrong on science, and actively dangerous to the health and quality of life of millions of people in pain. Medicare practice standards cannot ethically be based upon such a flawed foundation.

(2) Provisions of the CMS rule changes directly contradict draft recommendations of the HHS Inter Agency Task Force for Best Practices in Pain Management, summarized in their September 25-26 public meeting. A major thread in these recommendations is that there can be no one-size-fits-all therapy plan or threshold of risk for untoward outcomes from prescription of opioid pain relievers to chronic pain patients. There is widespread deep concern for the potential for deep harms to patients if such a threshold is imposed by mandate.

(3) The HHS Task Force is charged under 2016 CARA legislation to report its recommendations to Congress by May 2019. Additional legislation may be warranted in the implementation of their recommendations. Delay in implementing the published CMS rule changes is therefore warranted to ensure internally consistent, medically safe and evidence-based common standards of medical practice in pain management, for both Medicare patients and others under private insurance, affected by the influence of CMS standards among pharmacists and physicians.

Failings of the 2016 CDC Opioid Guidelines

As written, the 2016 CDC opioid guidelines are based upon three fundamental assumptions. These assumptions are -- at best -- unsupported by evidence, if not outright fraudulent:

(1) The US is said to have a public health crisis in opioid addiction and overdose mortality caused by physicians over-prescribing medical opioids to their patients. Restrictions and enhanced oversight of medical opioid prescriptions are therefore deemed to be warranted to prevent further exposure of both patients and their untreated family members to such potential sources of addiction and death.

(2) Opioid pain relievers are said to be ineffective for chronic pain, when used for months or years.

(3) Safe and reliable alternatives to opioid therapy are said to exist and are declared preferable as substitutes for opioid therapy.

A fourth fundamental weakness of the Guidelines is expressed as a systematic omission.

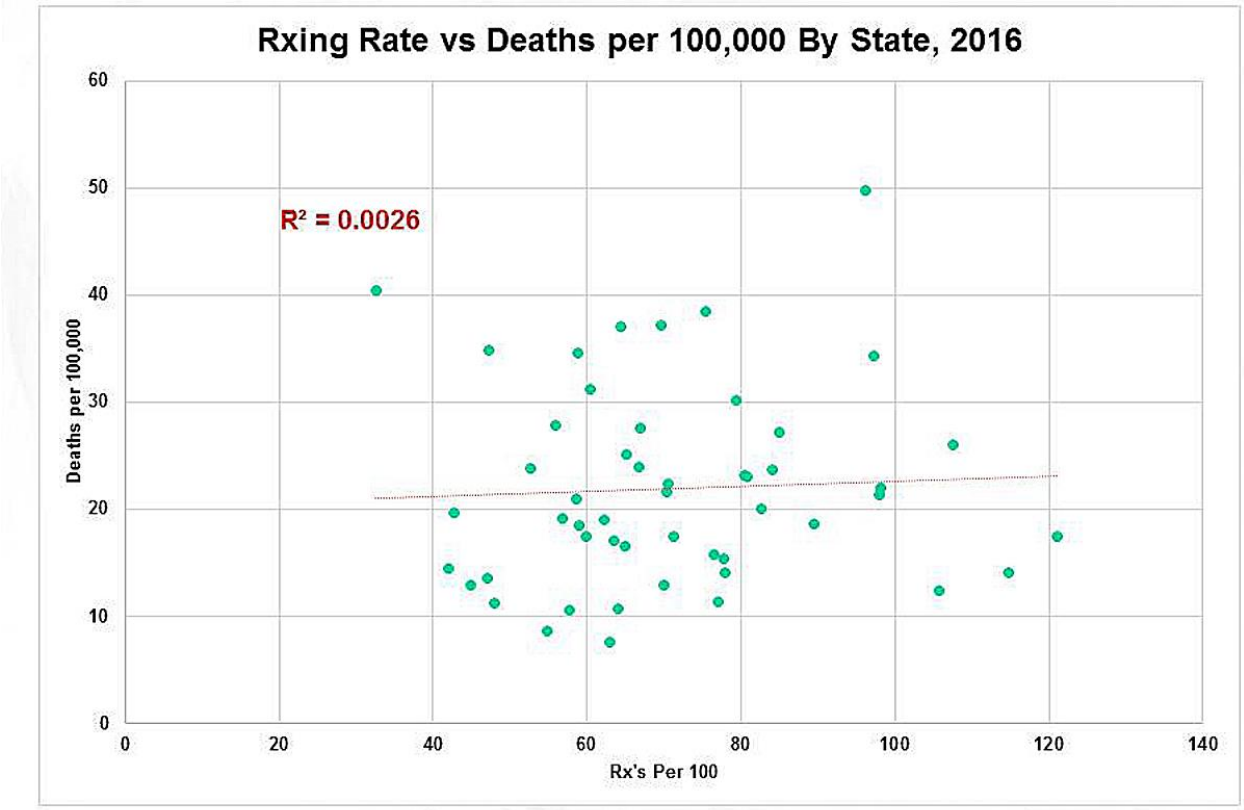
(4) The Guidelines are silent with respect to the practical impact of significant variations in opioid metabolism between individual patients, due to genetic polymorphism in six key liver enzymes affecting 90% of all prescription medication metabolism.

Published Evidence Contradicts the Opioid Guidelines

Each of the false assumptions or omissions in the CDC Guidelines is addressed by attachments to this letter and by embedded references.

Physician Over-Prescription as a Source of the Opioid "Crisis"?

If exposure to medical opioids was a significant driver in America's opioid crisis, then we should expect to see elevated rates of opioid overdose mortality among demographic groups which receive the highest rates of prescriptions. However, analysis of data published in the CDC Wonder Database and Agency for Healthcare Research and Quality HCUP Database shows no such trends.



Opioid prescription rates per 100 people by US State versus opioid-related deaths per 100,000. **No consistent trends, wide variations, very poor data fit.**

Figure 1: Prescribing Rates vs. Overdose Related Deaths by US State, 2016

Figure 1 was first published in "The Phony War Against Opioids – Some Inconvenient Truths", June 21, 2018, *The Crime Report* [author Richard A. Lawhern, Ph.D]. The data downloads and analysis report from which the Figure is extracted, are provided as Atch 1 and Atch 2 to this petition. These results were also briefed to the HHS Inter Agency Task Force, on May 30, 2018 and September 25, 2018 [see Atch 3 and Atch 4].

It is apparent from data published by the CDC itself, that the contribution of medically managed opioid prescriptions to overdose mortality is so small in comparison to illegal street drugs that it gets lost in the noise. This is true of all prescriptions – both those used by patients and when unused prescriptions are diverted to family members or others.

Moreover, as acknowledged by Dr Nora Volkow, Director of the National Institutes on Drug Abuse, the demographics of chronic pain and opioid abuse are largely disjoint. People with opioid addiction and people with chronic pain are quite different demographic groups.

[Nora D Volkow, MD, and Thomas A McLellan, Ph.D., "Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies" . *NEMJ* 2016; 374:1253-1263 March 31,

2016. http://www.nejm.org/doi/full/10.1056/NEJMra1507771]

Of particular interest from this reference is a quotation:

> "Unlike tolerance and physical dependence, addiction is not a predictable result of opioid prescribing. Addiction occurs in only a small percentage of persons who are exposed to opioids — even among those with pre-existing vulnerabilities ... Older medical texts and several versions of the Diagnostic and Statistical Manual of Mental Disorders (DSM) either overemphasized the role of tolerance and physical dependence in the definition of addiction or equated these processes (DSM-III and DSM-IV). However, more recent studies have shown that the molecular mechanisms underlying addiction are distinct from those responsible for tolerance and physical dependence, in that they evolve much more slowly, last much longer, and disrupt multiple brain processes.**"**]

Amplifying on Volkow and McLellan, there is evidence that opioid analgesics are in reality quite safe. Dasgupta et al report on a study with 2.2M subjects (North Carolinians) -- "…the largest population-based cohort study published to date." Death rate was 0.022% per year

> "Overdose mortality rates rose gradually at lower doses, and increased gradually at doses greater than 200 mg average daily MME. Like previous studies, a dose–response relationship between MME and mortality risk was observed, but there is new evidence that the shape of the curve is not linear. Unlike previous studies, there was no meaningful inflection of the incidence rate at 100 mg/day average daily MME. However, there appeared to be relatively small additional risk of overdose death after patients reach 200 mg average daily MME, relative to the lowest strata, on the log-linear scale.... "
>
> "The greatest limitation of this study stems from the inherent question of exchangeability when comparing patients at different doses of the same medication in observational studies. Patients receiving higher doses are more likely to have more serious illnesses which may necessitate higher doses...
>
> "Deaths involving opioid analgesics result from physiologic, genetic, and behavioral factors, compounded by broader social determinants such as health literacy, poverty, access to healthcare, and further upstream causes of painful conditions from injuries, cancer and violence. These characteristics may also influence the likelihood of receiving a prescription for an opioid analgesic."

[Nabarun Dasgupta, MPH PhD, Michele Jonsson Funk, PhD, Scott Proescholdbell, MPH, Annie Hirsch, MPH, Kurt M Ribisl, PhD, Steve Marshall PhD, "Cohort Study of

the Impact of High-Dose Opioid Analgesics on Overdose Mortality" *Pain Medicine*, Volume 17, Issue 1, 1 January 2016, Pages 85–98, https://doi.org/10.1111/pme.12907]

From the CDC Wonder Database, we find that seniors over age 50 are prescribed opioid pain relievers more than 250% more often than minors and young adults under 30 [op cit "The Phony War" and ATCH 1]. Yet opioid-related mortality rates in seniors have been stable for 17 years at the lowest levels in any age group, while overdose mortality among kids and young adults has skyrocketed. Also from CDC, we know that rates of opioid prescribing have dropped 50% since 2010 but rates of opioid-related mortality from all sources (legal prescriptions, diverted prescriptions or illegal street drugs) have more than doubled.

Restrictions on opioid prescribing simply don't work in a problem dominated by street drugs.

If medically managed opioids are contributing significantly to overdose rates, then we would expect to see higher opioid related mortality in US States with the highest rates of prescribing. But again, we do not. As apparent in Figure 1 above, when State by State prescribing rates are compared with mortality rates, we see no trend lines or correlation at all. In fact, the group (seniors) that benefitted most directly from liberalized prescribing policy prior to 2010 has shown no increased risk of opioid-related mortality. This fundamentally contradicts the cause and effect relationships assumed without supporting evidence by the CDC Guidelines writers.

These emerging demographic insights are reinforced by two landmark studies of post-surgical prescribing, published by reputable medical journals:

A 2018 study in the *British Medical Journal* examined outcomes among more than 586,000 patients prescribed opioids for the first time after surgery. Less than 1% continued renewing prescriptions longer than 13 weeks. 0.6% were later diagnosed with Opioid Abuse Disorder during follow-up periods averaging 2.6 years between 2008 and 2016. Likelihood of diagnosis increased with the length of prescriptions, but rose only modestly as dose levels increased from under 20 to over 120 MMED.

It is quite plausible that the diagnosis of Opioid Abuse Disorder in many of these patients was incorrect. The diagnosis is typically made by physicians who are without recourse to accepted definitions of the disorder such as the American Psychiatric Association Diagnostic and Statistical Manual, 5th edition. Many doctors who diagnose patients with abuse are general practitioners who lack training in addiction and have little experience evaluating the behaviors that actually define addiction. Likewise, some physicians confuse patient reports of emerging chronic pain – caused by failed surgery -- for drug seeking and potential opioid abuse.

During the period of the BMJ study, doctors increasingly became concerned with being sanctioned by law enforcement authorities for their use of opioid doses high enough to

reliably manage pain. Thus some physicians may have diagnosed drug abuse to protect themselves – not their patients, who were often summarily discharged.

[Gabriel A Brat, Denis Agniel, Andrew Beam, Brian Yorkgitis, Mark Bicket, Mark Homer, Kathe P Fox, Daniel B Knecht, Cheryl N McMahill-Walraven, Nathan Palmer, Isaac Kohane, "Postsurgical prescriptions for opioid naive patients and association with overdose and misuse: retrospective cohort study", *BMJ* 2018;360:j5790 *http://www.bmj.com/content/360/bmj.j5790.long*]

A 2016 study reported in the *Journal of the American Medical Society* tracked long-term opioid prescriptions in non-surgical patients, and compared prescription rates to 642,000 patients who received one of eleven common types of surgery. Opioid prescriptions were defined as "chronic" when 10 or more scripts were written in one year or a prescription was renewed continuously for more than 120 days.

In this study, the rate for chronic prescriptions of opioid analgesics among millions of non-surgical patients was estimated at 0.136 percent. (Parenthetically, this finding strongly suggests that "doctor shopping" is not a significant source of opioids abused by people with addiction.) For 4 of the 11 surgical procedures studied, the same rate of prescriptions occurred after surgery as before. For the 7 remaining procedures, long-term opioid prescriptions rose by 0.174% for caesarean delivery, up to 0.69% for total knee replacement.

The highest rate of post-surgical chronic prescriptions occurred for total knee replacement – a procedure known to cause lingering pain in many who undergo it. It is plausible that many on-going prescriptions after knee replacement reflected chronic post-surgical pain, rather than issues of opioid misuse. Although not assessed in the study, this outcome may also be true of other procedures for which long-term prescribing was observed.

[Eric C. Sun, Beth D. Darnall, Laurence C. Baker, Sean Mackey, "Incidence of and Risk Factors for Chronic Opioid Use Among Opioid-Naive Patients in the Postoperative Period", JAMA Internal Medicine 2016;176(9):1286-1293. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2532789]

In combination, these studies demonstrate beyond any reasonable contradiction that managed medical exposure does not by itself significantly increase risks of opioid abuse in surgical patients who are properly screened for previous opioid exposure. This outcome directly contradicts the false claim that addiction starts with just a few pain pills in any substantial number of people.

Are Opioids Ineffective in Chronic Pain?

Writers of the CDC Guidelines made this claim. However, the same writers attempted to cherry pick from the research literature, apparently to unfairly bias their results

against opioid therapy. They conflated a relative absence of long term trials for opioids, with an absence of evidence of effectiveness -- ignoring the reality that the shortage of long term trials reflects high drop-out rates among chronic pain patients randomized to placebo.

The CDC writers rejected from consideration, any opioid trial that did not last a year or more, while embracing trials reports from much shorter trials of non-opioid medication and behavioral therapies. They also failed to explicitly make clear the differences in criteria that they applied. These biases in the official record may reasonably be regarded as evidence of institutional malfeasance and fraud.

[Baraa O. Tayeb, Ana E. Barreiro, Ylsabyth S Bradshaw, Kenneth K H Chui, Daniel B Carr, "Durations of Opioid, Nonopioid Drug, and Behavioral Clinical Trials for Chronic Pain: Adequate or Inadequate?" *Pain Medicine*, Volume 17, Issue 11, 1 November 2016, Pages 2036–2046.
https://academic.oup.com/painmedicine/article/17/11/2036/2447887]

[See also: Stephen A. Martin, MD, EdM; Ruth A. Potee, MD, DABAM; and Andrew Lazris, MD, "Neat, Plausible, and Generally Wrong: A Response to the CDC Recommendations for Chronic Opioid Use", *Medium Corporation,* September 7, 2016
https://medium.com/@stmartin/neat-plausible-and-generally-wrong-a-response-to-the-cdc-recommendations-for-chronic-opioid-use-5c9d9d319f71]

[Also pertinent: Mark Edmund Rose, "Are Prescription Opioids Driving the Opioid Crisis? Assumptions vs Facts", *Pain Medicine*, December 17, 2017
https://doi.org/10.1093/pm/pnx048]

A more general observation may be added to this published record of CDC distortions. If opioid pain relievers are supposedly ineffective, then why (according to CMS itself) are 1.6 million Medicare patients -- and a similar number of private insurance patients -- being maintained on opioids at doses exceeding 90 MMEDD? This is an obvious and glaring oxymoron, and a basic contradiction direct from the medical evidence.

Are Alternatives or Replacements for Opioid Therapy Available and Preferable?

In a word, "no", they are not. Despite attempts to "spin" the results of limited Phase I and Phase II trials of non-invasive, non-pharmacological therapies by their proponents and by the AHRQ itself, the state of precision in medical trials literature for such proposed alternatives is abysmal. We literally do not know if these alternatives work any better than placebo.

At this time, not *one* of the various alternative pain therapies has undergone adequate Phase II trials, let alone Phase III trials. All are essentially experimental. Moreover, no alternative therapies have been trialed as "replacements" for opioid therapy; only as adjuncts. The state of current literature is summarized in the October print edition of

Practical Pain Management, in a critical review of the AHRQ Systematic Outcomes Review published in June 2018.

[Richard A Lawhern, Ph.D., and Stephen E. Nadeau MD, "Behind the AHRQ Report -- Understanding the limitations of "non-pharmacological, non-invasive" therapies for chronic pain." https://www.practicalpainmanagement.com/resources/practice-management/behind-ahrq-report]

[Andrea C. Skelly, Ph.D., M.P.H., Roger Chou, M.D. ,Joseph R. Dettori, Ph.D., M.P.H., M.P.T. Judith A. Turner, Ph.D. Janna L. Friedly, M.D. Sean D. Rundell, Ph.D., D.P.T. Rongwei Fu, Ph.D. ,Erika D. Brodt, B.S. ,Ngoc Wasson, M.P.H., Cassandra Winter, B.S. Aaron, J. R. Ferguson, B.A. "Comparative Effectiveness Review 209 - Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review" AHRQ Publication No. 18-EHC013-EF June 2018]

Significance of Genetic Polymorphism in Opioid Metabolism

The CDC writers group ignored a well-established medical literature that examines variations between individuals in their ability to metabolize (break down) opioid pain relievers. Six key liver enzymes are involved in the metabolism of 90% of all medications. Due to genetic polymorphisms, the expression of these enzymes can vary significantly between individuals. The result is that millions of patients are poor metabolizers of opioids, passing very low amounts of active breakdown products across the blood-brain barrier. Others are "hyper-active" metabolizers, in whom opioids pass through the body so rapidly that pain is reduced for only minutes rather than hours.

[Tom Lynch and Amy Price, "The Effect of Cytochrome P450 Metabolism on Drug Response, Interactions, and Adverse Events," *American Family Physician,* August 1, 2007 https://www.practicalpainmanagement.com/treatments/genetic-testing-pain-medicine-future-coming]

[Howard S Smith, MD, "Opiod Metabolism" *Mayo Clinic Proceedings,* 2009 Jul; 84(7): 613–624. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2704133/]

Both of these populations can potentially benefit from opioid therapy -- but not below the 90 MMED dose limit threshold recommended in the CDC Guidelines and widely enacted by insurance providers. Some pain management specialists identify a range of "minimum therapeutic dose" for opioids on the order of 20 to 1,000 MMED. There are published case reports of "hyper-dose" patients who do well on dose levels over 2000 MMED, with no unacceptable side effects or observed symptoms of addiction.

[Forest Tennant, MD, DrPH, "Ultra High Dose Opioid Therapy – Uncommon and Declining, but Still Needed." *Practical Pain Management,* May 2013. https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/ultra-high-dose-opioid-therapy-uncommon-declining-still-needed]

Potential Impact of CMS-Mandated Soft and Hard Edits

The CDC Guidelines have had such horrific results that some of the writers in the Core Expert's group and outside reviewers of the document have disavowed it. More recently, hundreds of medical professionals have directly opposed published changes in Medicare and Medicaid rules intended to implement CDC Guidelines as a mandatory standard of practice.

[Stefan Kertesz, et al, "An Opioid Metric Based on Dose Alone? 80 Professionals Respond to NCQA" *Medium,* March 22, 2017. https://medium.com/@StefanKertesz/an-opioid-quality-metric-based-on-dose-alone-80-professionals-respond-to-ncqa-6f9fbaa2338]

A group of over 200 medical professionals has recently signed a letter of petition to the Director of the CDC, demanding that an outcomes review be conducted and published for the 2016 CDC Guidelines. Such a review was recommended by the CDC Board of Scientific Advisors before publication of the Guidelines – but was not implemented in the Guidelines or since. Grounds for this demand include widespread damage done to hundreds of thousands of patients by the desertion of their doctors -- and in many cases outright refusal to treat pain with opioids, or to make patient referrals.

This damage has occurred despite the fact that the original CDC Guidelines were written as voluntary rather than mandatory, and were primarily directed to general practitioners. Following publication, the Director of the National Center for Injury Prevention and Control was at pains to issue a letter amplifying on the fact that the Guidelines were not intended to be mandatory. However, doctors, business managers and hospitals continue to interpret the guidelines as de facto mandatory standards -- the violation of which might expose doctors to sanctions (e.g. loss of clinical privileges) or legal liability. Predatory prosecution by the Drug Enforcement Agency and State authorities has largely validated this concern.

The public has every reason to expect similar outcomes from so-called "safety" audits mandated by CVS. In order to avoid sanctions by CMS and its contracted insurance providers, even more pharmacists and physicians will cease treating pain with opioids.

However, there is no published evidence for any positive outcome from mandated tapering of opioid dose rates. Hundreds of reports in social media and print venues relate stories of patient collapse and disability due to doctor desertion and denial of pain care. Evidence discussed before the September 25, 2018 meeting of the HHS Task Force on best practices in pain management indicates that such mandates have generated multiple patient suicides, particularly among Veterans. Some patients may be going into the street to find pain relief from dangerously adulterated street drugs, after they are denied treatment by their doctors. These trends can only accelerate in the hostile regulatory environment that will be created by the CMS soft and hard edits.

Conclusions:

1. CMS should immediately suspend Medicare rules imposing "Real-Time Care Coordination Safety Edits to Address Chronic Opioid Use," until at least January 2020, pending resolution of HHS Task Force recommendations to Congress on best practices in pain management and Congressional legislation responding to these recommendations.

2. CMS also needs to conduct an in-depth verification and validation of the attached analysis demonstrating the lack of relationship between rates of physician prescribing for opioids versus rates of overdose related mortality from all sources (prescriptions used by patients or diverted to others, as well as illegal street drugs). Results of this process should be published as guidance on further development of public policy. See Atch 1 and 2.

3. CMS should go on public record advocating for withdrawal of the 2016 Opioid Guidelines as medically inappropriate and dangerous to patient health. Rewriting should be performed in a publicly transparent process led by physicians with experience in community practice for pain management and supported by patients or their advocates as voting members of the writers group. Normally such a guideline would be developed by the US FDA rather than CDC.

Disclosures:

The author is a technically trained non-physician patient advocate, with 21 years experience in online peer to peer patient support groups, medical literature research and analysis. He has over 50 published papers and articles in public policy for opioid analgesics and treatment of chronic pain.

The Alliance for the Treatment of Intractable Pain is an all-volunteer network of over 300 medical professionals, media editors, writers, knowledgeable pain patients and caregivers. The Alliance receives no external funding and declares no professional or financial interests beyond supporting and advocating for balanced public policy which addresses the medical needs of people in agony. Although this submission has been shared with our members and associates -- many of whom have chosen to endorse the petition -- sole responsibility for the accuracy of content remains that of the author.

Some sections of the text compiled for this petition have previously been published in White Papers of the Alliance for the Treatment of Intractable Pain, available at http://www.face-facts.org/atip/

On August 25, 2018, the author of this petition independently filed a formal complaint with the HHS Office of the Inspector General, against the US Centers for Disease Control and Prevention. The author alleges a record of gross misbehavior, malfeasance and fraud on the part of CDC and its Center for Injury Prevention, on

grounds overlapping with the substance of this petition. The status of this complaint has not yet been reported out.

List of Attachments:

1. Analysis report: "US Opioid Prescribing vs Mortality V1.4" Richard A Lawhern Ph.D. and John Alan Tucker Ph.D., May 2018

2. Excel ™ Workbook: "Analysis of CDC Wonder Rx and ER Data V1.4" May 2018

3. Agenda for Development of Pain Management Best Practices, V1.1, Richard A Lawhern, Ph.D. Presented May 30, 2018 to the HHS Inter Agency Task Force.

4. HHS Task Force 2018-09 Final (Prepared Remarks), Richard A Lawhern PhD

Endorsements:

The following medical professionals endorse the content of this petition and support suspension of CMS "safety" edits.

Stephen E. Nadeau, MD University of Florida College of Medicine, Neurology	Richard L. Martin, Pharmacist Pain Management Consultant (retired) Pain Patient Advocate
Anne Fuqua, BS Nursing Intractable Pain Patient Senior Patient Advocate, ATIP	Jon Aumann Certification in Community Based Participatory Research. Biomedical Research Investigator
Cindy Willis Tipton Registered Nurse, Retired/Disabled	Gail Carlson Registered Nurse
Amanda Proctor President & CEO, Cauda Equina Foundation, Inc.	Deborah Touchshanks Nursing Student Intractable Pain Patient
Sandra St. John RN OCN, CHPN, CRNI, Retired Intractable Pain Patient	Jodi L Watson, RN BS Post-Acute Liaison Supervisor
Christine Dangel, RN	Kelli A Enyart Registered Nurse Chronic Pain Patient
Joyce E Dowling, LPN Retired/Disabled Intractable Pain Patient	Lisa K Kronus, CHPN, RN
Michael Springer, Registered Nurse and Nurse Practitioner	Rebecca Faure, RN, BSN
Kelly-Anne Brian, RN Intractable Pain Patient, 19 years	Catrina Byrge, RN Intractable Pain Patient
Janet Larsen, RN (retired) Sarcoidosis, fibromyalgia, osteoarthritis	Charles Bruscino 20-year advocate for injured workers

and rheumatoid arthritis patient	
Brenda Sosa-Johnson, AAS Medical Secretary, Intractable Pain Patient	C. Sue Stewart, LPN Intractable Pain Patient
Kristie R. Walters Medically Retired RN Intractable Pain Patient	Anita McCabe, RN
Linda Burke, Medical Social Worker Home Healthcare	Sean E Samitt, CPhT, MTM-C, RPT, BLS, ACLS, CSC
Cricket Fauset, RN, MS	Melissa Dobs, RN Medically retired Intractable Pain Patient
Sharon Thurow, FNP, BC	Tammy Kosbab EDS Wisconsin, Inc.
William Hurwitz, MD, JD	Cynthia Laux, RN Intractable Pain Patient Activist
Michelle Stratton, RN	Dr.Donald Hollis PhD Patient Advocate
Melissa Dobbs, MSN Intractable Pain Patient (36 years) Patient Advocate	Diane Sanor, RN Intractable Pain Patient
Jon Mankowski, LCSW Diplomate in Clinical Social Work	Betty Mackie CPP Medical Diagnostic Coder
Marguerite Moody, RN Operating Room Nurse	Ansam Groshang, Bachelor of Medicine, Bachelor of Surgery, (Iraq) Intractable Pain Patient

The following chronic pain patients, care givers and advocates also endorse the content of this petition and support suspension of CMS "safety" edits. Many of these patients have already been harmed by doctor desertion or coerced tapering of opioid therapy to below minimum therapeutic levels.

Heather Shall Wargo Intractable Pain Patient and Patient Advocate	Timothy E. Mason Research Chemist Chronic Pain Patient
Henry Yennie, MSW Chronic Pain Patient	Carla Cheshire Chronic Pain Patient
Sharon L. Anderson, Disabled Chronic Pain Patient 27 years	Roberta Glick, LCSW, Disabled Chronic Pain Patient 16 years
Jan Poole Chronic Pain Patient 19 years	Kristen D. Ogden Co-Founder/Co-Leader Families for Intractable Pain Relief (FIPR) Advocate and Caregiver for Intractable Pain Patient
Louis Ogden, Intractable Pain Patient	Mark D Adams Intractable Pain Patient

Shannon MacLeod Intractable Pain Patient	Evelyn Blackburn Co-founder, Oregon Pain Action Group
Melanie Spath Petrovcik Intractable Pain Patient	Pam Molnar Intractable Pain Patient
Rhonda Posey Pain patient advocate, Arachnoiditis Society for Awareness and Prevention	Audrey Liebl Former EMT, patient advocate, ambassador at PatientsLikeMe,
Lisa Doherty Intractable Pain Patient, 26 years	Pam Cushion Intractable Pain Patient
Michael Springer Intractable Pain Patient	Lori Marden, Senior Manager Corporate Healthcare Insurance Providers Intractable Pain Patient
Heidi Henley Intractable Pain Patient Advocate	Dinah Federer Rehabilitation Counselor (Retired) Caregiver for Intractable Pain Patient
Gregg Kervill, DipIM, MIIM, SMIEEE, NCE Intractable Pain Patient	Cynthia C Boyd Intractable Pain Patient
Claudine Bell Intractable Pain Patient	Jeff Creech Intractable Pain Patient
Skerry Skarvan Intractable Pain Patient	Donna Green Intractable Pain Patient
Carol Adams, LPN Disabled / Intractable Pain Patient	Ingrid Hollis, Co-Founder/Co-Leader of Families for Intractable Pain Relief.
Daniel Froehlich, caregiver	Matthew Guffan Patient Advocate
Judy Birchfield, Caregiver and Patient Advocate for a Disabled Intractable Pain Patient	Florence Jane Morris Intractable pain patient
Jeffrey A Creech Intractable Pain Patient	Amara Moon Founder and patient advocate Oregon Pain Action Group
Alexander Stevens Intractable Pain Patient	Anne Fuqua Patient Advocate
Chereese Ferriera Intractable Pain Patient	Christy Goldstein Intractable Pain Patient
Wendy Sinclair Intractable Pain Patient Co-Founder, Oregon Pain Action Group	Susan Stephenson Intractable Pain Patient
Stephanie Norton Intractable Pain Patient	Stormy Stebbins Intractable Pain Patient, Advocates
Maureen Murphy Intractable Pain Patient on Medicare	Trina Vaughn Intractable Pain Patient – Abandoned by Physicians

Patricia Davidson Intractable Pain Patient	Ramona Bushee Intractable Pain Patient
Christine Brasure Intractable pain patient, deserted by doctor in fear of losing his license	

Respectfully Submitted,