POSITION PAPER
Families for Intractable Pain Relief (FIPR)
May 6, 2018

– Urgent –
Emergency Care is Required for Non-Standard Patients by July 1, 2018

Subject: Proposal to Establish a Certification and Registration Program for Physicians to Provide Non-Standard Pain Care Including Opioid Analgesia

Problem: Lack of non-standard care for severe intractable pain patients nationwide

- There are severe intractable pain patients who do not respond to standard pain treatment.
- These patients are now losing access to opioid pain medications that have enabled effective management of severe pain, increased function, and improved quality of life.
- These patients suffer from rare, incurable disease conditions that cause extreme constant pain that has not responded to standard care. These rare conditions include adhesive arachnoiditis, reflex sympathetic dystrophy/complex regional pain syndrome (RSD/CRPS), autoimmune disease, post-viral neuropathy/encephalopathy, traumatic brain injury, and genetic diseases such as Ehlers-Danlos syndrome and Marfan syndrome.
- Many of these patients have genetic variants that affect their ability to metabolize medications and need higher than standard doses of medications and non-oral routes of administration.
- Many of these patients have been stable on their opioid medications for years; opioid medications are the treatment of last resort to manage their pain.
- It is estimated that less than 5% of chronic pain patients require non-standard care.

Background:

- The CDC Guideline for Prescribing Opioids for Chronic Pain issued in March 2016 was intended to provide voluntary guidelines applicable to primary care physicians
    - The Guideline has been widely misinterpreted as imposing mandatory dose ceilings.
    - Some state legislatures and medical boards have followed with laws and regulations imposing mandatory limits on doses and quantities.
    - "Standard pain care" has been de facto defined by the CDC Guideline to include non-pharmacologic, non-opioid pharmacologic, and opioid pain medications up to the level of 90 milligram morphine equivalent dose (MED).
    - Physician care for these severe pain patients, "outliers" whose treatment needs fall far outside a typical bell curve, is now scarce and approaching non-existent due to multiple factors.
        - Shortage of physicians
        - Lack of training for physicians to safely provide non-standard pain care
        - Physician fear of prescribing opioids due to intimidation by regulatory agencies, limits on private insurance and Medicare Part D coverage, and increasing risk of malpractice suits

    - Although the CDC Guideline and some state-imposed guidelines do not prohibit prescribing of higher doses of opioids when indicated, many physicians have totally stopped prescribing opioids, often with little or no warning to patients.
    - Most physicians still practicing as pain specialists are anesthesiologists who limit treatment to "standard care" and often use paraspinal corticoid injections and other invasive treatments in lieu of medication.
    - The CDC Guideline **did not** recommend forced tapering of opioid doses for long-term stable patients.
        - Physicians who participated in writing the CDC Guideline have spoken out against forced tapering, but so far to no avail.
- Tens of thousands of chronic pain patients have already lost their access to pain treatment and medications. More patients are suddenly losing access to care every day.
    - Abrupt cessation of medication or rapid tapering of medication can be life-threatening.
- Untreated or undertreated severe intractable pain leads to a bed-bound dysfunctional state and can lead to death from stroke, cardiac arrest, or adrenal failure.

FIPR Position:

- The facts about risks of opioid medications do not support the actions that have been taken by Congress, Federal agencies, state agencies, and insurance payers.
- **There is an urgent need to establish, initially on an emergency basis, a certification and registration program:**
    - That would authorize trained physicians to treat severe intractable pain as needed without restrictions on opioid dosing or duration of care, and without restrictions on non-oral routes of administration or the off-label use of non-opioid medications,
    - That would recognize such treatment as authorized exceptions to dose limits or thresholds imposed by CDC, DOJ/DEA, CMS, state laws and guidelines, and insurers,
    - That would authorize the filling of controlled drug prescriptions written by certified physicians across state lines, and
    - That would protect certified physicians from malpractice suits or other liability, provided the patient has consented in writing to non-standard care.
- Precedents exist for the establishment of special programs to ensure access to necessary treatment while avoiding drug diversion, abuse, and overdose. These include, for example, training and registration for prescribing of certain fentanyl products, licenses for clinics to prescribe methadone to addicts, and private physician certificates to provide buprenorphine (Suboxone) to opioid-dependent persons. We envision a similar program which would allow medical practitioners to treat non-standard pain patients safely and without fear of legal reprisal.
- Failure to establish an emergency authority to treat severe intractable pain patients with non-standard care will allow unnecessary suffering to continue and will lead to the death of previously stable pain patients.

Proposed program concept paper follows.

PROGRAM CONCEPT
Families for Intractable Pain Relief (FIPR)

– Urgent –

Emergency Care is Required for Non-Standard Patients by July 1, 2018

Title: Proposal to Establish a Certification and Registration Program for Physicians to Provide Non-Standard Pain Care Including Opioid Analgesia

Program Registrants:
Any licensed physician or a nurse practitioner or PharmD with a supervising physician may voluntarily register as a "non-standard pain care provider." Non-standard pain care may include off-label use of opioid and non-opioid medications and non-standard routes of administration. Certified practitioners will be authorized to prescribe opioid pain medication at doses that exceed dose limits or thresholds imposed by CDC, DOJ/DEA, CMS, state laws and guidelines, and insurers.

Registration Authority:
State Medical Boards, Nursing Boards, etc. and FDA or DOJ/DEA

Requirements to Register:
The practitioner will address the following in their registrant application:

1. Qualifications including applicable post-graduate medical training, MD, nurse practitioner or PharmD (with MD supervision), and special training on non-standard care for pain patients.
2. Description and eligibility of the patients to be treated.
3. Methods used to treat including opioid dosages, use of non-opioid pharmaceuticals, and routes of administration, both oral and non-oral.
4. Number of patients to be treated.

Practitioner Data:
Location:
Hours of Operation:
Pharmacy Utilization:

Records:
Specific records will be kept:

1. History
2. Physical
3. Documentation of standard treatment failure
4. Treatment plan
5. Periodic visits/progress notes
6. Evaluation
7. Consultation
8. Laboratory Data including urine, blood toxicology
9. REMS
10. As required by Federal and state rules

Contact FIPR/Kristen Ogden/804-731-2072

Freedom from pain, to the extent achievable, is a fundamental human right!

Plan for Noncompliance:
A plan for discharge or other corrective action should be described for patients found to have aberrant behaviors such as positive urine test, overdose, diversion, failure to attend or pay fees.

State Inspection:
The registrant accepts that State agencies can monitor and inspect the practice.

Reports to State:
The registrant will report a yearly registration list of patients to the governing agency.

Practitioner Fee:
Registrants will pay an annual fee to help cover program costs.

Oversight Committee:
The State governing body should appoint a working oversight committee composed of representatives from law enforcement, public health, and physicians who are themselves registrants who provide non-standard care.

Non-Exempt Issues:
Nothing in this registration exempts a practitioner from following all laws and regulations governing controlled substances.

Summary and Recommendations:

The need to provide non-standard pain care to a number of severe intractable pain patients is extremely urgent. The number of patients without access grows daily, including loss of care by long-term stable patients. Loss of treatment is clearly resulting in agony, loss of function and quality of life, and a shortened life-span for some of these tragic individuals.

Recommendation 1: That FDA adopt emergency regulations to implement this program immediately for a period of one year or until a permanent program can be established.

Recommendation 2: That a permanent program as described be implemented through FDA regulation or Federal law to ensure access to necessary pain care, including high-dose opioid treatment and other non-standard treatment, is available to all patients who require such care.

Position paper and program concept prepared by Kristen Ogden and Ingrid Hollis, Co-founders/Co-leaders, Families for Intractable Pain Relief (FIPR) with professional medical input and review by Dr. Forest Tennant, MD, DrPH, Veract Intractable Pain Clinic.

Contact FIPR/Kristen Ogden/804-731-2072

Freedom from pain, to the extent achievable, is a fundamental human right!