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www.CoastalPainGroup.com

Wellness Opioid Safety Package Treatment Agreement & Informed Consent

Please note you can find this and other information at our website

www.CoastalPainGroup.com

Patient name: _____ DOB: _____

OPIOID TREATMENT AGREEMENT AND INFORMED CONSENT

By signing this agreement, I affirm that I have read and understand the Opioid Treatment Agreement and was provided Informed Consent. I have the full right and power to be bound by this agreement and that I have read, understood and accepted these terms. **Non-compliance of the agreement can be terms for discontinuation of opioid therapy and possible dismissal from the practice and that treatment may be discontinued without** agreement by the patient. A copy of these agreements is available upon request and on our practice website.

Patient Signature _____ Date: _____

OPIOID SAFETY PACKAGE

By signing this agreement, I state I have read and was given the Opioid Safety Package. I understand it has valuable information for my safety and detailed office policies that I must abide by. A copy of this packet is available upon request and on our practice website.

Patient Signature: _____ Date: _____

Opioid Risk Tool

Please ONLY ✓ check the box if the category applies to you

		Office Use Only	
		Do Not Mark Here	
		<i>f</i>	<i>m</i>
<input checked="" type="checkbox"/>	Do you have anyone in your FAMILY who has ABUSED		
	Alcohol?	1	3
	Illegal drugs?	2	3
	Prescription drugs?	4	4
	Do you have PERSONAL history of substance ABUSE of		
	Alcohol?	3	3
	Illegal drugs?	4	4
	Prescription drugs?	5	5
	Are you between the age of 16-45?		
	Yes	1	1
	Do you have PERSONAL history of preadolescent sexual abuse?		
	Yes	3	0
	Do you have PERSONAL history of psychological disease?		
	Attention Deficit Disorder, Obsessive Compulsive Disorder, Bipolar, Schizophrenia	2	2
	Depression	1	1
	NONE OF THE ABOVE CATERGORIES APPLY TO ME	0	0

OPIOID SAFETY AND INFORMATION

Opioid therapy is not suitable for every patient. However, for some this may be a reasonable option. It is best to try non-opioid therapies before considering opioid therapy. We advise you to understand the benefits, risks, and alternative options before starting opioid therapy. We have put together extensive resources to provide patients with the information needed to stay safe and continue to benefit from their pain management program. Your treatment plan will be combined with non-opioid therapies, as appropriate. It is important that you establish specific treatment goals to improve pain and function.

Patients considering opioid therapy must undergo a trial of opioid therapy to determine if the benefits of improved function and decrease pain outweigh the risk of continued opioid therapy. You will be required to sign a treatment agreement with our practice. It is your responsibility to read your treatment agreement and informed consent before starting opioid therapy. The agreement clearly specifies that you will only receive opioid or other controlled medications from Coastal Pain and these will usually be in association with a monthly office visit for therapeutic drug monitoring and appropriate medical supervision. To ensure the highest level of safety and good outcomes, please follow all office policies in your treatment agreement and in this opioid safety package. You can find a copy of the treatment agreement on our website or request a copy at the front desk. Safety monitoring will include but not limit to routine urine drug screening, pill counts and CURES monitoring. Only use medications as prescribed.

You should NEVER take more than prescribed and taking more medications than prescribed increases the risk of significant adverse events such as death. You must lock up all your opioid medications in a safe.

You are REQUIRED to complete our online safety course called Opioid Safety Program. The online course covers the risk, benefits and alternative options with regards to opioid therapy. Some of the concerns and side effects with the use of opioid therapy include: physical dependence, tolerance, opioid induced hyperalgesia, abuse, addiction, respiratory depression, sedation, over dose. Other adverse side effects include constipation, mood swings, weight gain, depression, dry mouth leading to cavities and other dental issues, immune system dysfunction, hypogonadism, low testosterone and estrogen, osteoporosis, chronic fatigue, sexual dysfunction, impairment of motor skills that can affect driving and other tasks. etc. Please note: it is illegal and unsafe to drive or operate heavy machinery while impaired. If at any point the risks outweigh the benefits for you to continue opioid therapy, we will provide you with a discontinuation plan that typically involves a slow titration off opioid therapy by approximately 10% per week or as tolerated. Please note there is limited evidence as to the benefits of long-term opioid therapy.

We do not recommend the consumption of alcohol while on opioid therapy. We also strongly recommend you do not start any benzodiazepine therapy or consider talking to your PCP about discontinuing them. Alcohol, benzodiazepines, marijuana and other sedative medications can increase your risk of respiratory depression and death when combined with opioid therapy. The FDA has released a black box warning with regards to the co-use of opioids and benzodiazepines (such as valium, Xanax, Clonazepam) which can lead to accidental overdose and death. Suddenly stopping benzodiazepines can be life threatening. Avoid grape fruit juice due to increased medication interactions and side effects.

STRICT OFFICE POLICIES OF PRIORITY

All patients are required to follow the treatment agreement and office policies. These documents are available online as well as upon request. Failure to comply with your treatment agreement will place you at an increased risk of adverse events with the use of opioid therapy, such as overdose, death, and may subject you to discontinuation of opioid therapy as an option in your treatment plan. Always remember that our treatment goal is to work together to improve your quality of life and function at the lowest effect dose of opioid medications.

DO NOT VIOLATE THE FOLLOWING RULES

- 1) NO EARLY REFILLS: NEVER TAKE MORE THAN PRESCRIBED. IF YOUR PRESCRIPTION STATES UP TO 4 TIMES A DAY AS NEEDED FOR PAIN, THAT MEANS YOU CAN TAKE UP TO 4 PILLS OVER A 24 HOUR PERIOD AS NEEDED FOR PAIN. NEVER TAKE 5 PILLS IN ONE DAY REGARDLESS OF A PAIN FLARE. YOU MAY BE SUBJECT TO RANDOM PILL COUNTS TO ENSURE YOU ARE NOT TAKING MORE THAN PRESCRIBED.
- 2) CURES: WE CHECK THE DEA DATABASE REGULARLY WHICH LISTS ALL OPIOID MEDICATIONS PRESCRIBED. DO NOT FILL OUTPATIENT OPIOID MEDICATIONS FROM OTHER PROVIDERS, SUCH AS DENTISTS, PCP, ER, SURGEONS, ETC.
- 3) URINE DRUG SCREENING (UDS): WE CHECK URINE DRUG SCREENS TO MAKE SURE YOU ARE ONLY TAKING THE OPIOID MEDICATIONS PRESCRIBED TO YOU. NEVER TAKE A FRIEND'S MEDICATION. NEVER TAKE OLD MEDICATION EVEN IF WAS PRESCRIBED TO YOU IN THE PAST. IF YOU ARE PRESCRIBED AN OPIOID MEDICATION THAT DOES NOT SHOW UP IN AN UDS YOU WILL BE REQUIRED TO PROVIDE AN EXPLANATION. IT COULD BE CONSIDERED A VIOLATION WITHOUT A REASONABLE EXPLANATION FOR THE NON- PRESENCE OF A PRESCRIBED MEDICATION.
- 4) 30 DAY REFILL POLICY: WE TYPICALLY PROVIDE YOU A PRESCRIPTION THAT IS TO BE USED OVER A 30 DAY PERIOD. YOU ARE NOT ALLOWED TO CONSUME A 30 DAY SUPPLY OF MEDICATIONS IN 28 OR 29 DAYS. WE UNDERSTAND DUE TO PHARMACY ISSUES AND OTHER FACTORS PATIENTS MAY PICK UP THEIR NEXT PRESCRIPTION ON DAY 28 OR 29. IF SO, WE EXPECT THAT YOU DO NOT OPEN THE NEXT PRESCRIPTION BOTTLE UNTIL DUE ("DAY 31"). YOU ARE RESPONSIBLE FOR KEEPING TRACK OF WHEN YOUR NEXT PRESCRIPTION IS DUE AND WHEN YOUR BOTTLE CAN BE OPENED. NO EXCUSES WILL BE ACCEPTED FOR DEVIATION OF THIS POLICY. PLEASE BRING YOUR PRESCRIPTION BOTTLES TO EACH VISIT.
- 5) OPIOID SAFETY COURSE: YOU ARE REQUIRED TO COMPLETE OUR ONLINE SAFETY COURSE AT WWW.COASTALPAINGROUP.COM.

NALOXONE PRODUCT PRESCRIPTION FOR OPIOID OVERDOSE TREATMENT

With the rise in concern for opioid deaths due to overdose and rise in opioid prescriptions over the years, the CDC has recommended that physicians prescribe take-home emergency treatments such as Naloxone for opioid overdose to patients and family members. Any person can request these Naloxone devices regardless of whether they are taking opioid medications or not. Whether or not you decide to obtain a Naloxone overdose product please be familiar with the OPIOID OVERDOSE TREATMENT OUTLINE below. Full version is available online. If you wish to obtain one of these products please let your provider know and they will provide you a prescription to take to your own pharmacy of choice.

TAKE THE FOLLOWING STEPS IF YOU SUSPECT AN OPIOID OVERDOSE

STEP 1: CALL FOR HELP and DIAL 911. SEEK IMMEDIATE MEDICAL ATTENTION.

STEP 2: CHECK FOR SIGNS OF OPIOID OVERDOSE

Signs of OVERDOSE and/or OVERMEDICATION, which often results in death if not treated, include:

- 1) Mental confusion, slurred speech, intoxicated behavior
- 2) Nodding off during conversation or activity
- 3) Unusual or Extreme sleepiness, inability to awaken verbally or upon sternal rub
- 4) Breathing problems or respiratory distress
- 5) Slow to shallow breathing in a patient that cannot be awakened
- 6) Fingernails or lips turning blue/purple.
- 7) Small "pinpoint" pupils
- 8) Slow heartbeat and/or low blood pressure
- 9) Hearing the "death rattle": an exhaled breath with a very distinct, labored sound coming from the throat

STEP 3: SUPPORT THE PERSON'S BREATHING: Start rescue breathing which can be very effective in supporting respiration. Start full CPR if needed.

STEP 4: ADMINISTER NALOXONE: Naloxone can be given intranasal with the NARCAN Nasal Spray or intramuscular (into the muscle) injection with EVZIO.

Once patient starts breathing independently, put them in the "recovery position" on the side and always stay with the patient and keep them warm. Do not put in cold bath due to risk of drowning and do not try to make the patient vomit the drugs due to risk of choking or aspiration.

IF YOU DECIDE TO OBTAIN A NALOXONE PRODUCT PLEASE BE FULLY FAMILIAR WITH ITS ADMINISTRATION INSTRUCTIONS AS EACH DEVICE IS DIFFERENT. IF NEEDED, PLEASE ASK YOUR PHARMACIST OR YOUR PROVIDER FOR ASSISTANCE ON UNDERSTANDING THE DEVICE.

CONSERVATIVE THERAPIES & EVALUATIONS TO CONSIDER

Non-opioid treatment options are important for you to always consider from time to time in your treatment plan regardless if you have tried and failed them in the past. You should think of your treatment plan as a Bowl of Soup. It is reasonable to have opioid therapy as one of your ingredients in your recipe if the benefits outweigh the risk, however you also want to include when possible other healthy ingredients such as acupuncture, exercise, cognitive therapy. Risk of chronic opioid therapy can increase with certain conditions like sleep apnea, end organ failure and depression, therefore it is also important to consider evaluations for such conditions as needed and to inform your provider if you develop any changes in your health. Please consider the following recommendations:

1. INTEGRATED MEDICINE: Integrated medicine incorporates a variety of services such as: ACUPUNCTURE, MASSAGE, NATUROPATHICMEDICINE. These treatments can help increase function and decrease your pain scores.
2. PAIN PSYCHOLOGY: Addressing the mental health component of chronic pain is very important. Services provided typically by pain psychologist include: COGNITIVE THERAPY/ BIOFEEDBACK/ DEPRESSION TREATMENT.
3. ADJUVANT MEDICATIONS: Using topical creams and other non-opioid therapies can help reduce you need for opioid therapy and provide pain relief that can be safe and effective. If you have not tried these non-opioid therapies please inform your provider so they can discuss with you some possible topical cream options to add to your pain treatment plan.
4. HOME EXERCISES/PHYSICAL THERAPY: It is important that you consider staying mobile and consider some form of home exercise. You can also request formal physical therapy from your provider. Daily exercise can help with weight loss which will help lower your pain.
5. BACK BRACE: Back support devices such as back braces can be very helpful with certain activities such as gardening or house hold chores. You do not want to overuse a back brace. Typically, it is reasonable to use a back brace for about 2 hours. Ask your provider if it is an option for you.
6. SLEEP STUDY: If you suspect you snore heavily at night or have day time sleepiness it is important you consider a sleep study and possible CPAP use. Sleep studies are also important in identifying other sleep disorders.
7. ANNUAL PHYSICAL EXAM: IT IS IMPORTANT TO HAVE AN ANNUAL PHYSICAL EXAMINATION WITH YOUR PRIMARY CARE DOCTOR. YOU SHOULD INFORM US IF YOU DEVELOP OR HAVE ANY LUNG, HEART, LIVER OR KIDNEY DYSFUNCTION AT ANY POINT IN YOUR CARE. ORGAN FAILURE CAN INCREASE ADVERSE EVENTS WITH OPIOID THERAPY.
8. DEPRESSION SCREENING: CHRONIC PAIN OFTEN IS ACCOMPANIED BY DEPRESSION AND IT IS IMPORTANT YOU INFORM US IF YOU HAVE ANY UNTREATED DEPRESSION OR SUICIDAL THOUGHTS AT ANY POINT IN YOUR CARE SO WE CAN GET YOU THE HELP YOU NEED.

TO REQUEST ANY OF THE RECOMMENDATIONS ABOVE OR OTHER REQUEST, PLEASE INFORM YOUR PROVIDER AT YOUR NEXT OFFICE VISIT. THANK YOU FOR READING THIS PACKAGE FULLY. TOGETHER WE CAN IMPROVE YOUR QUALITY OF CARE AND DEVELOP A HIGH LEVEL OF SAFETY.

Treatment Agreement & Informed Consent

Consent for Chronic Opioid Therapy

I understand that my provider may recommend opioid medicine, sometimes called narcotic analgesics, to treat my pain. These medications may be recommended because my pain complaints are moderate to severe and other treatments have not sufficiently helped my pain. I understand that medications can have interactions with opioids that can either increase or decrease their effect. I confirm I have told my provider about all other medicines and treatments that I am receiving. I understand my responsibility for safe medication use and not taking more than prescribed. I understand the dangers of using opioids in combination with alcohol, cannabis, benzodiazepines or other substances that cause sedation, unless closely monitored by the prescriber.

I will promptly advise my provider if I start to take any new medications or have new treatments. I have been honest and told my provider about any personal or family drug and alcohol history use or abuse. I understand that the initiation of a narcotic/opioid medication is a trial. Continuation of the medication is based on evidence of benefit to me from, associated side effects of, and compliance with instructions on, usage of the medication. I am hereby informed that continuation and any changes in dosage of the medication will be determined by pain relief, functional improvement, side effects, and adherence to usage restrictions. Lack of significant improvement, the development of adverse side effects, or other considerations may lead my provider to discontinue the treatment or change dosage. Please note there is an increased risk of overdose and side effects if you have underlying kidney, liver, heart or lung disease while on opioid therapy. I understand to inform my provider if I have or ever develop any of these conditions. I understand that there is limited evidence as to the benefits of long-term opioid therapy. I understand that the complete elimination of pain is not to be expected.

Please note as part of your informed consent you have the right not to start opioid therapy. You can consider in the place of or in conjunction with opioid therapy alternative therapies to help you with your pain. These include non-opioid medications, physical therapy, acupuncture, etc. Please visit the online course **MyPainTools** for further non-opioid therapy options. All treatment modalities have associated risk and benefits. I understand that the possible complications of opioid therapy include:

- Constipation, Dry Mouth, Cavities, Nausea, Vomiting, Decreased Appetite
- Muscle Twitches, Sweating, Itching, Dizziness, Tiredness, Light Headedness, Sleepiness
- Respiratory Depression, Trouble Breathing, Interaction with Other Medications, Severe Weakness
- Difficulty with Urination, Decreased Sex Drive and Sexual Dysfunction, Seizures, Unconsciousness
- Hypogonadism with Secondary Osteoporosis, Depression, Risk of Substance Use Disorder
- Physical Dependence and Addiction, Risk of impaired motor skills affecting driving and other tasks
- Over Dosage, Slow Reflexes, Confusion and Death, Allergic Reaction, Swelling of Throat or Face
- Chronic opioid use in Pregnant Females may pose serious risks to the fetus, therefore contact your provider immediately if you are or suspect you may become pregnant
- Hyperalgesia: which is a condition of increase in pain due to the use of opioid medications

Inform your provider about any side effect that you may experience. More information and other risk of opioid therapy can be found on our website: Opioid Safety Course, which you are required to complete.

OPIOID TREATMENT AGREEMENT

This agreement is important for you to have a safe and controlled pain treatment plan. Opioids have a high potential for abuse and they can be dangerous or cause death if used in the wrong way. Use medication at a greater rate may result in discontinuation of opioid therapy.

1. I agree to follow the dosing schedule prescribed to me, I will **NEVER** take more medication than prescribed regardless of a pain flare, and will call the office or go to ER/Urgent care for any uncontrolled pain flares.
2. I will **NEVER** share, sell or exchange my medication with anyone for any reason.
3. I understand that opioid medications are addictive, habit forming and can lead to overdose.
4. I understand that my pain medications will not get rid of all my pain and part of my treatment plan is to reduce my need for pain medications, restore function, have specific goals and make safety a priority.
5. I understand I will get past health records from other offices as needed and hand deliver to the office.
6. I understand I must inform all my doctors if I become pregnant at any time during my care.
7. I understand I will not consume alcohol or use illicit drugs while I am taking pain medications.
8. I understand the black box warning and increased risk of death with the use of Benzodiazepines or other sedative medications while I am taking opioid therapy and will try to avoid them when possible.
9. I understand that I am solely responsible for the safe keeping of my medications and will keep my medications locked up in a secure safe and ensure they are not stolen or taken by others or children.
10. I understand opioids should be disposed of properly based on local city and states regulations.
11. I understand having certain conditions such as sleep apnea, depression, and mental illness can increase risk of serious adverse effects and will be honest with my provider if I have or develop these conditions.
12. I understand that **ALL** medication refills involving opioid medications require a scheduled appointment with a Coastal Pain Provider, and phone request for opioid medication refills will NOT be honored. I understand that if I run out of my opioid medications due to overuse or loss of medications I may not be able to obtain early refills. I understand opioids are habit forming and suddenly stopping them can lead to withdrawal and other adverse effects. I understand I may be required to go the Emergency Room/Urgent Care if I experience any adverse effects from not having my medications. (Allow 3-5 days for non-narcotic medications)
13. I understand that it is at provider's discretion to replace LOST, STOLEN OR DAMAGED medications. Such situations will subject my case to a thorough committee review and a police report may be required. I understand my provider is not required to release medications early due to vacation.
14. I understand that I should not drive or operate heavy machinery while I am taking medications that cause drowsiness, making me less alert or impairing my cognitive function. I am aware that I must be fully alert and ensure that I am safe before I drive or operate machinery.
15. I understand I will bring unused medication to the office visit if a change in medication is requested.
16. I agree to notify my provider if I experience any adverse effects or dosage problems with my prescribed medications. I may be asked to bring any unused medication to your appointment for review.
17. If I experience any of the following serious side effects: Allergic Reaction, Trouble Breathing, Swelling Of Face Or Throat, Seizures, Severe Weakness, and/or signs of Unconsciousness I will stop taking the narcotic medication and seek immediate emergency medical attention.
18. My provider may routinely obtain Patient Activity Reports from the California Department of Justice, called CURES report, which provides a list of all controlled medications that are filled at all pharmacies.
19. I understand I should not request outpatient opioid pain medications from other providers or the Emergency Room/Urgent Care. I will inform my physician each time I visit the Emergency Room/Urgent Care. I will inform all other providers who are part of my care that I have an opioid treatment agreement with our clinic.
20. As a pain management patient, I acknowledge that I will be subject to random Urinalysis, Serum Toxicology and/or Pill Counts. I understand that there will be an additional cost of the Urinalysis/ Serum Toxicology that I will be responsible for. If the results of the screen test positive for illegal drugs, and/or do not reflect medicine prescribed by my doctor, I understand that I may be referred for further assessment and/or further opioid therapy may be discontinued with possible discharge from the practice. Additional services and lab work, such as Urine/Blood Drug Screens (UDS)

will be billed separately from the standard visit charge.

21. I know that I may be asked to bring any or all of my prescribed medications to my office appointment or at a random time for a Pill Count. I understand to follow all directions for all treatments including referral to other modalities such as PT, cognitive therapy, imaging studies and outside referrals.
22. I understand my provider may refer me to addictionology for Opioid Safety evaluation and education.
23. I understand that my provider may write opioid medication prescriptions on a 30 day basis. To receive another opioid medication prescription, I must schedule another office visit within 30 days (but no sooner than 28 days) of the date on my current prescription, so my doctor can properly evaluate my progress. Exceptions may be made at the provider's discretion only.
24. I understand that even if I pick up my next prescription from the pharmacy on for example "Day 28", that I may not start the new prescription bottle before "Day 31".
25. I understand that my regular monthly medication refills will NOT be honored after regular business hours, over weekends or holidays. In rare exceptions, a small amount may be written to meet the next appointment.
26. The prescribing provider has my permission to discuss all diagnostic and treatment details with my dispensing pharmacist or any professional who provides me healthcare for the purposes of maintaining accountability.
27. I will keep regular appointments and will call at least 24 hours in advance if I must reschedule or cancel.
28. I understand that medications may not be given for cancelled or no-show appointments. I understand that I must have an appointment to be seen in the office.
29. The Clinic's phone M.A. Line hours are from 7:30 am to 4:00 pm, Monday through Friday for **NON- EMERGENCY medication questions and refill requests.** I understand that the Clinic has a 24 hour Emergency Line and if for some reason I am unable to reach a provider that I will immediately go to the Emergency Room for evaluation and treatment if I have an urgent or emergent issue.
30. I understand that abusive behavior or harassment toward any staff member or provider will not be tolerated. The clinic will determine what actions can be considered harassment on a case-by-case basis and, if warranted, I can be dismissed from the practice. I understand that dealing with a forged, falsified or altered prescription will result in my **immediate dismissal** from the practice.
31. I understand I will obtain prescribed opioids from only one clinician or practice.
32. I authorize CPS and my pharmacy to cooperate fully with any city, state or Federal Law Enforcement Agency, including the state's Board of Pharmacy, in the investigation of any possible misuse, sale or other diversion of my pain medicine. I authorize CPS to submit a copy of this agreement upon request. I agree to waive any applicable privilege or right of privacy or confidentiality with respect to these authorizations.
33. The risks and potential benefits of opioid medication therapies and/or procedures were explained to me and I acknowledge that I have received such explanations.
34. I understand that "overdose" is a risk with opioid therapy which can lead to death and that a prescription for a Naloxone Product to treat overdose is available upon request. I understand that I take responsibility if I overdose accidentally or on purpose. I agree to go online and read the Opioid Overdose section of the Opioid Safety Course and that your provider strongly recommends you educate and teach family members regarding the use of Naloxone Products for overdose.
35. I understand I am required to complete the free Online Opioid Safety Course which explains in detail the alternatives, risks and benefits with chronic opioid therapy.
36. **I attest that I am not a risk to myself or others and I will inform the office immediately if I develop suicidal thoughts and/or seek immediate care in the emergency room.**
37. I agree to use only **one** pharmacy for my pain-related medications. In the event, that circumstance require use of another pharmacy; I will notify my provider immediately with all pertinent contact information.