**Definition of “Opioid Failure”**

1. **Are serious opioid adverse effects occurring?**
The Safe Rx Santa Cruz County Committee/work group concluded that *serious opioid adverse effects are considered to be those that are potentially fatal, or those that are unmanageable.* Examples of potentially fatal adverse effects are inadvertent overdose or respiratory failure. Examples of unmanageable opioid adverse effects would be narcotic bowel syndrome, opioid-induced hyperalgesia, or severe sleep apnea in patients who are intolerant to CPAP or Bi PAP. The committee noted that placing this question first (as opposed to focusing on aberrant behaviors) was important to establish a patient-centered approach to the definition of opioid failure.

2. **Is the patient taking medications as prescribed?**
The committee reached consensus that considering this question would allow clinicians to elicit information regarding opioid-related aberrant behaviors (ORABs) from the patient with less bias and judgment. We struggled to define the decision point for determining opioid failure from this vantage point, given the complexity and wide variation seen in opioid-related aberrant behaviors (ORABs), ranging from requests for early prescription refills to opioid diversion, “chemical coping” with trauma and stress, to overt opioid use disorder/“addiction.” The importance of cultural humility and concern in identifying and managing ORABs was emphasized, adding additional challenges to this decision point. There was consensus among the clinicians that certain ORABs could result in immediate discontinuation of opioid prescribing: for example, *evidence of illegal activities*, such as opioid diversion and selling medications or behaviors with *acute risk of danger*, such as concurrent use of other medications or alcohol, with high risk of harm. Other behaviors, such as repeated requests for early refills or monopolization of the majority of clinician-patient interactions by opioid-related matters, were acknowledged as being significant concerns, but in and of themselves were not felt to be of sufficient weight to indicate opioid failure. The committee opted to facilitate the recognition of ORABs by the busy clinician by presenting a list of possible ORABs in a pyramid graphic (figure one), with the most concerning ORABs at the apex “red zone” warranting immediate discontinuation of opioid prescribing followed by ORABs of lesser concern in the “orange zone” underneath. The number of “orange zone” ORABs demonstrated by an individual patient before opioids would be considered to have failed is left to clinical judgment.

![Figure one: Opioid-related aberrant behaviors](image-url)
Various validated assessment tools were noted (COMM, SOAP, ORT, DIRE) and while felt to include helpful information, were felt to be too unwieldy to incorporate into an efficiently utilized clinical definition of opioid failure.

Although not behaviors, certain risk factors should be noted to increase the risk of ORABs:
- Past or current history of substance use disorder
- Family history of substance use disorder
- History of psychiatric illness
- Poor social support
- History of pre-adolescent sexual abuse

3. Are treatment goals of chronic opioid therapy being achieved?

The committee agreed that the use of a numeric 1-10 scale to assess analgesia is often misleading in chronic pain patients – implying that the goal should be “zero pain.” The committee emphasized that the goal of chronic pain treatment should primarily be to improve function, and not simply a reduction in pain score. Minimal reductions in pain scores can be associated with significant improvement in function, and conversely large drops in pain scores can be linked to a low functional status. Concrete functional goals for chronic opioid therapy are best set at the start of treatment, and over-reliance on patient self-reporting alone for functional improvement should be avoided.

In order to assess whether or not treatment goals of chronic opioid therapy are being achieved for a patient, the committee recommends asking the patient two general questions:

"Over the past month, on average, has your opioid treatment provided adequate relief from your pain?"

"Over the past month, on average, has your opioid treatment permitted satisfactory general function?" (Ideally, input to this second question should be obtained from the patient’s family and friends as well as of the patient.)

If the answer to either/both of these questions is “no” then consideration should be given to the possibility that opioids have failed, especially if function is not satisfactory. Before concluding that opioids have failed the patient, however, consideration should be given to whether an adequate dose and length of time of opioid therapy been attempted.

4. Has an adequate dose and length of time of opioid therapy been attempted?

The maximum opioid doses recommended in recent chronic opioid therapy guidelines range from 50 to 120 oral morphine equivalents per day (MED). In establishing what the committee felt should be considered an adequate trial of chronic opioid therapy for the purposes of defining opioid failure, the recently released CDC guidelines were considered to be a primary reference. Two factors were considered: the dose levels at which further increases were associated with significant increase in risk of significant adverse effects, and the dose levels at which the benefits for pain control and functional improvement were incremental. The committee opted to set an oral morphine equivalent per day (MED) dose at 50mg as a dose that represents an adequate dose. This is consistent with the 2016 CDC guidelines.

The duration of opioid treatment that the committee felt constituted an adequate trial attempted to balance the recognized practicalities of dose titration in a busy clinical practice with data that
show patients who remain on opioids for greater than 90 days are much more likely to remain on opioids years later, and that absence of clinically meaningful pain relief within one month of starting treatment are unlikely to experience pain relief with longer-term use. The committee felt that 45 days was adequate time for dose titration while minimizing chronic opioid exposure in patients for whom it was failing. It was recognized that the majority of chronic opioid therapy “legacy” patients will have been on chronic opioid therapy for much longer than 45 days and be at significantly higher doses than 50mg MED.