

HOSPITAL AND HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA–HOSPITAL IMPROVEMENT INNOVATION NETWORK (HAP HIIN) ORGANIZATION ASSESSMENT OF SAFE OPIOID PRACTICES

As a **high-alert medication** class, opioids bear a heightened risk of causing significant patient harm when used in error.¹ Errors with opioids have led to serious adverse events, including allergic reactions, failure to control pain, oversedation, respiratory depression, seizures, and death.² According to data from various error reporting programs, opioids, particularly morphine, HYDROMORPHONE, and fentaNYL, are among the most frequent high-alert medications to cause patient harm.^{3,4}

Proactively assessing safety practices, especially those involving opioid use, can provide hospitals with valuable information about the weaknesses that exist within their medication-use system. Because the harm from errors involving opioids is potentially devastating, identifying the risks associated with opioid use should be considered a priority by healthcare organizations.

This tool will help you assess the safety of opioid practices in your facility and identify opportunities for improvement.

Instructions for Completing the Assessment

Please note:

It is important for each hospital in a multihospital system to complete the assessment *individually*.

1. **Establish an interdisciplinary team** consisting of the following (or similar) roles:

- Chief medical officer
- Nurse executive
- Director of pharmacy
- Clinical information technology specialist
- Medication safety officer/manager
- Risk management and quality improvement professionals
- At least two staff nurses from different specialty areas
- At least two staff pharmacists (one clinical and one distribution)
- At least one active staff physician who regularly orders opioids

Your team should be provided with sufficient time to complete the assessment and be charged with the responsibility to evaluate, accurately and honestly, the current status of opioid practices in your facility. Because medication use is a complex, interdisciplinary process, *the value and accuracy of the assessment is significantly reduced if it is completed by a single discipline involved in medication use.*

2. **Read and review the assessment in its entirety (including the instructions) before beginning the assessment process.**

Each team member should be provided with either a hard copy or electronic version of the assessment and the definitions for review before the first team meeting.

¹Institute for Safe Medication Practices. ISMP list of high-alert medications in acute care settings [online]. 2014 [cited 2015 Dec 1]. <http://www.ismp.org/Tools/institutionalhighAlert.asp>

²Institute for Safe Medication Practices. High-alert medication feature: reducing patient harm from opiates. *ISMP Med Saf Alert Acute Care* 2007;12(4):1-3. Also available <http://www.ismp.org/newsletters/acutecare/articles/20070222.asp>

³Hicks RW, Santell JP, Cousins DD, et al. MedMARX 5th anniversary data report: a chartbook of 2003 findings and trends 1999-2003. Rockville (MD): United States Pharmacopeia Center for the Advancement of Patient Safety; 2004.

⁴Institute for Safe Medication Practices Canada. Top 10 drugs reported as causing harm through medication error [online]. *ISMP Canada Saf Bull* 2006 Feb 24 [cited 2015 Dec 1]. <http://www.ismp-canada.org/download/safetyBulletins/ISMPCSB2006-01Top10.pdf>

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Instructions for Completing the Assessment (continued)

3. **Verify your demographic information.** Before the first team meeting, the team leader should complete this section and, if necessary, verify any responses with hospital administration. All demographic questions must be answered.
4. **Convene the team.** During the evaluation process, ensure that each team member can view the assessment during the meeting by providing each member with a printed hard copy of the assessment and definitions.
5. **Discuss each assessment item.** As necessary, investigate and verify the level of implementation with other healthcare practitioners outside your team. When a consensus on the level of implementation for each assessment item has been reached, select the appropriate choice. For the majority of the assessment items, your hospital will have the following options: Not implemented, Partially implemented, and Fully implemented.

Key: Please use the following key and guidelines to select the most appropriate response:

- Not implemented: This item has *not* been implemented within the hospital.
- Partially implemented: This item has been *partially implemented in some or all areas* of the hospital, or this item has been *fully implemented in some areas* of the hospital.
- Fully implemented: This item has been *fully implemented throughout the hospital*.

Hospitals may want to consider assigning an individual to record any discussion generated around each assessment item and the rationale behind the selected choice.

Definitions: Within the assessment, defined terms are highlighted throughout the text in bold letters. Definitions are provided on the last page of this tool.

For all assessment items: Unless otherwise stated, assessment items refer to opioids prescribed, dispensed, and administered to all inpatients and outpatients typically seen in most hospitals, including patients admitted to the emergency department and ambulatory surgery/procedure units.

- **For assessment items with multiple components:** : The choice of “Fully implemented” should be selected only if *all components* are present in *all areas* of the hospital. If only one or some of the components have been partially or fully implemented in some or all areas of the hospital, the response “Partially implemented” should be selected.
- **For assessment items with an option of “Not applicable”:** Select “Not applicable” *only* if your hospital meets the statement that follows. For example, for assessment item #3, only select “Not applicable” if your hospital does not have pain management protocols.

6. **Repeat the process outlined in step 5 for all assessment items.** All assessment items must be answered. *Save the paper copy* of your hospital’s assessment.

7. **If you have any questions, please contact:**

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Adapted with permission from the Institute for Safe Medication Practices, Horsham, Pennsylvania.

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DEMOGRAPHIC QUESTIONS

1. Please select the *one category* that best describes the number of inpatient beds currently set up and staffed for use in your hospital.

Fewer than 100 beds

100 to 299 beds

300 to 499 beds

500 beds and over

2. Please select the *one category* that best describes the type of service that your hospital provides to the majority of its admissions.

General medical and surgical

Specialty: pediatric

Long-term acute care

Specialty: psychiatric

Specialty: cardiology

Specialty: rehabilitation

Specialty: oncology

Specialty: women and children

Specialty: orthopedic

Other:

3. Which of the following services does your hospital provide? (Select all that apply.)

Oncology services (select even if chemotherapy is administered infrequently)

Pediatric services (select even if pediatric care is provided only in the emergency department and/or outpatient surgery)

Neonatal intensive care unit (select for any level of service)

Trauma services (select for any level of service)

Transplant services

None of the above

4. Is your hospital accredited?

No

Yes

Who accredits your hospital?

The Joint Commission

Healthcare Facilities Accreditation Program (HFAP)

Det Norske Veritas (DNV)

Other:

CONTINUED...

5. Is a pharmacist available in the hospital 24 hours a day, seven days per week to review orders and dispense medications?

No

Please specify how many hours a day a pharmacist is available.

Monday through Friday: hours

Saturday and Sunday: hours

Yes

6. Please select the *one category* that best describes the type of medication administration records (MARs) used at your hospital?

Handwritten MARs

Paper MARs printed from the pharmacy information system

Electronic MARs

7. Does your hospital use **bar-coding technology**?

No, we do not have bar-coding technology in our organization.

Yes

Please select the *one category* that best describes your hospital's use of bar-coding technology.

Bar-coding technology is used *only* in the pharmacy for drug selection.

Bar-coding technology is used *only* at the patient bedside for medication administration.

Bar-coding technology is used *both* in the pharmacy and at the patient bedside.

8. Does your hospital use **smart infusion pumps** with computer software that is capable of alerting the user to unsafe doses for continuous opioid infusions? (This question does *not* apply to patient-controlled analgesia [PCA] therapy.)

No, we do not have smart infusion pumps in our organization.

Yes

9. Does your hospital use a **computerized prescriber order entry (CPOE)** system?

No, we do not have CPOE in our organization.

Yes (Answer items a and b below.)

Please select the *one category* that best describes the area(s) where CPOE is used.

All inpatient areas

Emergency department only

CPOE is used in both the inpatient areas and the emergency department.

Other:

CONTINUED...

10. Does your hospital use automated dispensing cabinets (ADCs; e.g., Pyxis, Omnicell) to store opioids in patient care areas?

No, we do not have ADCs in our organization.

Yes (Answer questions a, b, and c below).

a. Please select *all* areas where opioids are stored in ADCs.

- | | |
|-------------------------------|------------------------------------|
| Catheterization lab | Oncology units |
| Dialysis | Operating room |
| Emergency department | Outpatient ambulatory care clinics |
| Endoscopy | Pediatric units |
| Intensive care units | Postanesthesia care unit (PACU) |
| Labor and delivery units | Radiology |
| Medical-surgical units | Same-day surgery/pre-op |
| Neonatal intensive care units | Other: |
| Newborn nursery | |

b. Please select the *one* statement that best describes the primary drug distribution model in those areas.

ADCs are used only for controlled substances and common “as needed” (PRN) medications.

ADCs are used for controlled substances, common PRN medications, and most first doses.

ADCs are the primary means of medication distribution (i.e., most medication doses are obtained from this source).

c. Please select *all* patient care areas that have active “profiling” functionality available and turned on (i.e., opioids cannot be accessed from the ADC without an order review by a pharmacist, with the exception of a limited supply of drugs needed for emergent situations).

- | | |
|---|------------------------------------|
| No areas have active “profiling” functionality available and turned on. | Newborn nursery |
| Catheterization lab | Oncology units |
| Dialysis | Operating room |
| Emergency department | Outpatient ambulatory care clinics |
| Endoscopy | Pediatric units |
| Intensive care units | PACU |
| Labor and delivery units | Radiology |
| Medical-surgical units | Same-day surgery/pre-op |
| Neonatal intensive care units | Other: |

11. What types of clinical decision support are available in the pharmacy information system and are used by pharmacists when processing orders for opioids? (Select all that apply.)

Dose range checking for maximum *single* doses

Dose range checking for maximum *total daily* doses

Hard stops (catastrophic stops) for doses known to cause serious harm

CONTINUED...

12. Does your hospital have an interdisciplinary pain management team?

No

Yes

Which disciplines are represented on the pain management team? (Please select all that apply.)

Anesthesia provider

Pharmacist

General surgeon

Social worker

Nurse

Other:

Oncologist

13. Which opioids are used for parenteral pain management in your hospital? (Select all that are used. This question does not apply to PCA therapy.)

fentaNYL

morphine

HYDROmorphone (Dilaudid®)

Other:

meperidine (Demerol®)

14. What is the *primary* opioid prescribed for parenteral pain management in your hospital? (Select one choice. This question does not apply to PCA therapy.)

fentaNYL

morphine

HYDROmorphone (Dilaudid®)

Other:

meperidine (Demerol®)

Not applicable: We do not have a *primary* opioid prescribed for parenteral pain management.

ASSESSMENT ITEMS

Organizational Structure

1. Current pain management protocols and guidelines for opioid use are available to guide prescribers, pharmacists, and nurses when opioids are prescribed, dispensed, administered, and monitored.

Not implemented

Partially implemented

Fully implemented

2. The organization uses a standardized pain scale(s) appropriate to the patient population to assess a patient's level of comfort or pain. For example, a numerical scale of 0 to 10 is used for conscious adults; Wong-Baker FACES® scale is used for pediatric patients; and FLACC (face, legs, activity, cry, consolability) scale is used for infants.

Not implemented

Partially implemented

Fully implemented

3. Pain management protocols define **opioid-naïve** and **opioid-tolerant** patients and outline the differences in the management of these patients.

Not implemented

Partially implemented

Fully implemented

Not applicable: Our hospital does *not* have pain management protocols.

4. A limited variety of opioids, concentrations of each opioid, and formulations of each opioid are included on the hospital formulary.

Not implemented

Partially implemented

Fully implemented

CONTINUED...

5. Equianalgesic dosing charts for oral, parenteral, and transdermal opioids (e.g., fentaNYL patches) have been established and are easily accessible to all practitioners when prescribing, dispensing, and administering opioids.

Not implemented Partially implemented Fully implemented

Prescribing

6. Standardized protocols or order sets are used to prescribe oral and parenteral opioids. (This question does not apply to PCA therapy.)

No

Yes (Please answer a and b below.)

a. Recommended doses for parenteral opioids are listed on protocols or order sets to guide appropriate dosing of opioids.

Not implemented Partially implemented Fully implemented

b. Order sets with opioid doses also contain orders for naloxone and directions for use.

Not implemented Partially implemented Fully implemented

7. Patients are screened for the following elements that might affect the dose, monitoring parameters, or appropriateness of opioid use. (Select all elements for which patients are screened.)

- | | |
|--|-----------------------------------|
| Age | Obstructive sleep apnea |
| Allergies | Opioid status (naïve or tolerant) |
| Altered mental status | Renal function |
| Asthma or chronic obstructive pulmonary disease | Weight |
| Concomitant use of other sedating medications (e.g., other opioids, benzodiazepines) | |

8. Range-of-dose orders for parenteral opioids (e.g., morphine 1 to 2 mg intravenously every 2 hours PRN pain) include the organization's approved pain scale to help nurses determine the appropriate dose to administer (e.g., give 1 mg for moderate pain [scale 4 to 7] and 2 mg for severe pain [scale 8 to 10]).

Not implemented Partially implemented Fully implemented

Not applicable: We do *not* allow range-of-dose orders.

9. Parenteral opioid orders include the mg/kg or mcg/kg dose for pediatric patients along with the total calculated patient-specific dose (e.g., morphine 0.1 mg/kg x 15 kg = 1.5 mg intravenously every 4 hours PRN severe pain).

Not implemented Partially implemented Fully implemented

Not applicable: We do *not* provide care to pediatric patients, even in our emergency department.

10. Long-acting opioids (e.g., fentaNYL patches, MS Contin® 100 and 200 mg tablets, OxyCONTIN® doses greater than 40 mg) are restricted for use in **opioid-tolerant** patients and are not used for acute pain management.

Not implemented Partially implemented Fully implemented

11. When prescribing an opioid, prescribers review the patient's active medication list and limit the number and variety of concurrent opioid orders.

Not implemented Partially implemented Fully implemented

12. A pain management specialist (e.g., physician, pharmacist, nurse practitioner) or pain team is consulted for patients with complex pain management issues (e.g., patients whose pain is difficult to control, patients with chronic pain, other high-risk patients).

Not implemented Partially implemented Fully implemented

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Order Review, Compounding, and Product Storage

13. Pharmacists have easy access to the patient's opioid status (**opioid-naïve** or **opioid-tolerant**) and take it into consideration when profiling or reviewing orders for opioids.

Not implemented Partially implemented Fully implemented

14. Pharmacists evaluate the patient's current medication profile for concurrent opioid use during order verification.

Not implemented Partially implemented Fully implemented

15. Concentrations of parenteral opioid infusions for *adult* patients are standardized to a single concentration per drug and are used in at least 90% of the cases.

Not implemented Partially implemented Fully implemented

16. Concentrations of parenteral opioid infusions for *pediatric* patients (including neonates) are standardized to a single concentration per drug and are used in at least 90% of the cases.

Not implemented Partially implemented Fully implemented

Not applicable: We do *not* provide care to pediatric patients, even in our emergency department.

17. Pharmacy purchases commercially available parenteral opioid infusions or prepares opioid infusions in the pharmacy (i.e., nurses do not prepare opioid infusions).

Not implemented Partially implemented Fully implemented

18. A pharmacist double-checks *all* opioid products before they are dispensed from the pharmacy, including those opioids placed into ADCs.

Not implemented Partially implemented Fully implemented

19. An **independent double check** is performed for *all* parenteral opioids that are compounded in the pharmacy. (One of the checks *must* be done by a pharmacist.)

Not implemented Partially implemented Fully implemented

20. Storage of highly concentrated opioid products (e.g., bulk containers of parenteral and oral liquids) is restricted to the pharmacy and certain units (e.g., oncology units).

Not implemented Partially implemented Fully implemented

21. The pharmacy prepares patient-specific doses of concentrated oral opioid liquids in oral syringes.

Not implemented Partially implemented Fully implemented

22. Morphine and HYDROmorphine are segregated from one another in *pharmacy* storage.

Not implemented Partially implemented Fully implemented

23. Morphine and HYDROmorphine are segregated from one another in *clinical unit* storage.

Not implemented Partially implemented Fully implemented

24. **Tall Man letters** are used to differentiate look-alike opioid names (e.g., HYDROmorphine and morphine) on the following. (Select all that apply)

- | | |
|---|---|
| ADC screens | Pharmacy-prepared medication labels |
| Drug listings in computer order entry systems (pharmacy or prescriber order entry/verification systems) | Protocols or order sets |
| MARs | Smart infusion pump screens |
| Medication bin labels | Not applicable: We do not use Tall Man letters . |

CONTINUED...

25. Parenteral opioid products stocked in patient care units are available in the least number of doses, concentrations, and forms that will meet essential patient needs between replenishment (not to exceed 72 hours).

Not implemented Partially implemented Fully implemented

Administration and Monitoring

26. Please answer a and b below.

a. *Prior* to the administration of *oral opioids*, nurses perform a baseline assessment of the following.

(Select all that are assessed.)

Blood pressure	Pain level (using the hospital-designated pain scale)
Heart rate	Quality of respirations
Last dose of an opioid or other sedating agent	Respiratory rate
Level of sedation	Other:

Not applicable: A baseline assessment is not routinely performed prior to administering oral opioids.

b. *Prior* to the administration of *parenteral opioids*, nurses perform a baseline assessment of the following.

(Select all that are assessed.)

Blood pressure	Pain level (using the hospital-designated pain scale)
Capnography	Pulse oximetry
Heart rate	Quality of respirations
Last dose of an opioid or other sedating agent	Respiratory rate
Level of sedation	Other:

Not applicable: A baseline assessment is *not* routinely performed prior to the administration of *parenteral* opioids.

27. Please answer a and b below.

a. *After* the administration of *oral* opioids, nurses perform a postadministration assessment within the hospital-designated time frame of the following. (Select all that are assessed.)

Blood pressure	Quality of respirations
Heart rate	Respiratory rate
Level of sedation	Other:

Pain level (using the hospital-designated pain scale)

Not applicable: An assessment is *not* routinely performed following the administration of *oral* opioids.

b. *After* the administration of *parenteral* opioids, nurses perform a postadministration assessment within the hospital-designated time frame of the following. (Select all that are assessed.)

Blood pressure	Pulse oximetry
Heart rate	Quality of respirations
Capnography	Respiratory rate
Level of sedation	Other:

Pain level (using the hospital-designated pain scale)

Not applicable: An assessment is *not* routinely performed following the administration of *parenteral* opioids.

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28. Patients are assessed for the use of fentaNYL patches on admission or entry into the hospital.

Not implemented Partially implemented Fully implemented

29. The location and removal of fentaNYL patches is clearly documented on the MAR/patient chart.

Not implemented Partially implemented Fully implemented

Not applicable: we do *not* use fentaNYL patches.

30. For *parenteral opioids*, an **independent double check** is performed with each new infusion bag, bottle, or bolus dose.

Not implemented Partially implemented Fully implemented

31. For *parenteral opioids*, an **independent double check** is performed with each change in the rate of infusion.

Not implemented Partially implemented Fully implemented

32. Naloxone and accompanying guidelines for the reversal of opioid toxicity are readily available wherever opioids are administered.

Not implemented Partially implemented Fully implemented

33. Discharge criteria have been established for outpatient areas (including the emergency department and procedural areas) that delineate the minimum amount of time that a patient must be monitored after receiving parenteral opioids (and before discharge).

Not implemented Partially implemented Fully implemented

34. The following are tracked to monitor adverse drug events with opioids. (Please select all that apply.)

Administration of naloxone	Patient falls
Adverse drug reaction reports	Pharmacy interventions
Medication event reports	Rapid response team calls

Assessment Items Related to Intravenous PCA

35. Is intravenous PCA therapy used in your hospital?

No — Please skip the remaining assessment items. This completes the safe opioid practices assessment for organizations that do not use PCA.

Yes — Please answer assessment items #36 through #48.

36. Which opioids are prescribed for intravenous PCA in your hospital? (Please select all that are used.)

fentaNYL	morphine
HYDROmorphone (Dilaudid®)	Other:
meperidine (Demerol®)	

37. What is the *primary* opioid prescribed for intravenous PCA in your hospital? (Please select *one* choice.)

fentaNYL	morphine
HYDROmorphone (Dilaudid®)	Other:
meperidine (Demerol®)	Not applicable: We do <i>not</i> have a primary opioid prescribed for intravenous PCA.

CONTINUED...

38. Patients are screened for the following elements, which might affect the dose, monitoring parameters, or appropriateness of PCA use. (Select all elements for which patients are screened.)

- | | |
|--|-----------------------------------|
| Age | Obstructive sleep apnea |
| Allergies | Opioid status (naïve vs tolerant) |
| Altered mental status | Renal function |
| Asthma or chronic obstructive pulmonary disease | Weight |
| Concomitant use of other sedating medications (e.g., other opioids, benzodiazepines) | |

39. Standardized protocols or order sets are used for PCA.

No

Yes (Please answer a and b below.)

a. Recommended doses for PCA opioids are listed on protocols or order sets to guide appropriate dosing of opioids.

Not implemented	Partially implemented	Fully implemented
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b. Order sets with PCA also contain orders for naloxone and directions for use.

Not implemented	Partially implemented	Fully implemented
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40. PCA basal infusion rates are *not* routinely ordered for **opioid-naïve** adult patients.

Not implemented	Partially implemented	Fully implemented
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41. PCA infusion concentrations are limited to no more than one or two concentrations per drug.

Not implemented	Partially implemented	Fully implemented
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42. **Smart infusion pumps** with computer software that is capable of alerting the user to unsafe opioid doses (i.e., soft and **hard stops**) are utilized when PCA is administered?

Not implemented	Partially implemented	Fully implemented
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43. *Prior* to the administration of opioid PCA, nurses perform a baseline assessment of the following. (Select all that are assessed.)

- | | |
|--|---|
| Blood pressure | Pain level (using the hospital-designated pain scale) |
| Capnography | Pulse oximetry |
| Heart rate | Quality of respirations |
| Last dose of an opioid or other sedating agent | Respiratory rate |
| Level of sedation | Other: |

Not applicable: A baseline assessment is *not* routinely performed prior to the administration of opioids with PCA therapy.

44. *During* the administration of PCA, nurses perform ongoing assessments within hospital-designated time frames of the following. (Select all that are assessed.)

- | | |
|---|-------------------------|
| Blood pressure | Pulse oximetry |
| Capnography | Quality of respirations |
| Heart rate | Respiratory rate |
| Level of sedation | Other: |
| Pain level (using the hospital-designated pain scale) | |

Not applicable: An assessment is *not* routinely performed during the administration of opioids with PCA therapy.

CONTINUED...

45. For PCA administration of *parenteral* opioids, an **independent double check** is performed with each new infusion bag, bottle, or bolus dose.

Not implemented Partially implemented Fully implemented

46. For PCA administration of *parenteral* opioids, an **independent double check** is performed with each change in the rate of infusion.

Not implemented Partially implemented Fully implemented

47. Patients, family members, and visitors are educated about the dangers of any individual, other than the patient, pressing the PCA activation button to deliver a medication dose (i.e., PCA by proxy).

Not implemented Partially implemented Fully implemented

48. Patients are educated about the postoperative use of PCA before surgery, unless it is a surgical emergency.

Not implemented Partially implemented Fully implemented

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DEFINITIONS

Bar-coding technology	Technology that reads bar codes with a computerized reading device, such as a scanner or imager.
Computerized prescriber order entry (CPOE)	A computer system into which prescribers enter medical orders, including orders for medications.
Hard stop (catastrophic stop)	Clinical alert in electronic systems (e.g., infusion pumps, order entry systems) that notifies the user that something is out of range or incorrect and prevents them from continuing. The alert cannot be overridden, and the user must start the process over from the beginning.
Independent double check	A procedure in which two individuals, preferably two licensed practitioners, separately check each component of the work process. For example, the components two individuals would independently check when administering an opioid infusion would include: patient identity (using two patient identifiers); drug and base solution, drug concentration, and rate of infusion on the pharmacy label; pump channel selection; pump settings (e.g., drug, concentration, rate); and line attachment.
Opioid-naïve	Patients who do not meet the definition of opioid-tolerant and who have not taken opioid doses at least as much as those listed for opioid-tolerant patients for one week or longer.*
Opioid-tolerant	Patients who are taking, for one week or longer, at least: 60 mg oral morphine/day; 25 mcg transdermal fentaNYL/hour; 30 mg oral oxyCODONE/day; 8 mg oral HYDROmorphine/day; 25 mg oral oxymorphone/day; or an equianalgesic dose of any other opioid.*
Smart infusion pump	An infusion pump with computer software that is, at a minimum, capable of alerting the user to unsafe dose limits and programming errors if standard concentrations and dose limits have been programmed into the pump's library.
Tall Man letters	Refers to the use of mixed-case letters to help draw attention to the dissimilarities of certain look-alike drug name pairs. The Institute for Safe Medication Practices maintains a list of recommended Tall Man letters at http://www.ismp.org/Tools/tallmanletters.pdf .

* Source: U.S. Food and Drug Administration. Extended-release (ER) and long-acting (LA) opioid analgesics risk evaluation and mitigation strategy (REMS) [online]. 2015 Jun [cited 2015 Dec 1]. <http://www.fda.gov/downloads/drugs/drugsafety/postmarketdrugssafetyinformationforpatientsandproviders/ucm311290.pdf>

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