

Key Messages & Responsive QA: Proposed Rule: General Hospital and Personal Use Devices: Renaming of Pediatric Hospital Bed Classification and Designation of Special Controls for Pediatric Medical Cribs; Classification of Medical Bassinet and Designation of Special Controls for Medical Bassinets

October 7, 2015

SECTION I: BACKGROUND

On October 8, 2015, the FDA issued a proposed rule to clarify the classification regulation of pediatric medical cribs, establish a separate classification regulation for medical bassinets, and put forward special controls which would impose safety requirements to address potential risks associated with pediatric medical cribs and medical bassinets used in health care, home, and child care settings. If the rule is finalized, these special controls will establish new safety requirements for pediatric medical cribs and medical bassinets, including standards for the width of and spacing between the slats in medical cribs and mattress flammability. The FDA believes that these requirements are necessary to provide reasonable assurance that pediatric medical cribs and medical bassinets are safe and effective.

The purpose of the proposed rule is to:

- provide continued access by prescription use to pediatric medical cribs with drop side rails in a home, child care or other facility when it is medically necessary;
- further reduce potential risks associated with pediatric medical cribs and medical bassinets, such as entrapment or fire;
- align applicable safety requirements for pediatric medical cribs with those of cribs for non-medical uses; and
- provide manufacturers with clarity about FDA's safety expectations and requirements by providing more specific design requirements for pediatric medical cribs and medical bassinets.

Helpful Links

- [FDA's Proposed Rule on Medical Cribs and Bassinets](#)
- [FDA Information on Medical Cribs Used in Homes and Child Care Settings](#)
- [CPSC's Crib Information Center](http://www.cpsc.gov/en/Safety-Education/Safety-Education-Centers/cribs/Coordinate-a-Safe--Sound-Zone/) (http://www.cpsc.gov/en/Safety-Education/Safety-Education-Centers/cribs/Coordinate-a-Safe--Sound-Zone/)
- [CPSC's Crib Standards](http://www.cpsc.gov/en/Newsroom/News-Releases/1973/CPSC-Sets-Crib-Safety-Standards/) (http://www.cpsc.gov/en/Newsroom/News-Releases/1973/CPSC-Sets-Crib-Safety-Standards/)
- [CPSC's Questions and Answers on the New Crib Standards](http://www.cpsc.gov/onsafety/2011/06/the-new-crib-standard-questions-and-answers/) (http://www.cpsc.gov/onsafety/2011/06/the-new-crib-standard-questions-and-answers/)

SECTION II: TOP LINE MESSAGES

1. The FDA is proposing special controls which would impose safety requirements to help prevent risk of injuries associated with pediatric medical cribs and medical bassinets.
2. The FDA's proposed rule would permit the use of drop-rail cribs outside of health care settings if medically necessary and prescribed by a health care professional.

SECTION III: KEY MESSAGES

Key Message #1: The FDA is proposing special controls which would impose safety requirements to help prevent risk of injuries associated with pediatric medical cribs and medical bassinets.

- The proposed special controls requirements seek to reduce risks to pediatric patients associated with pediatric medical cribs, such as entrapment and strangulation due to slat width and spacing; falls due to unsecure latches and other locking mechanisms; pinching, cuts, splinters and foreign body ingestions caused by compromised surface material; and burns due to mattress flammability.
- The safety requirements also address health risks associated with medical bassinets, such as tipping of the device, mattress flammability, and cracks in the plastic material (crazing), which may result in injuries such as bruises, burns, and cuts.
- Once the proposed rule is finalized, pediatric medical cribs may be made available outside of traditional health care settings by prescription.
- These requirements would formalize certain safety measures many manufacturers have already made to address these risks.

Key Message #2: The FDA’s proposed rule would permit the use of pediatric medical cribs outside of traditional health care settings if medically necessary and prescribed by a health care professional.

- This proposal allows continued use of pediatric medical cribs outside of traditional health care settings, such as in the home and child care facilities, if they are prescribed by a physician for use by a particular pediatric patient.

SECTION IV: RESPONSIVE Q&A

Q1. What is the FDA proposing?

A1. The FDA is proposing to:

- Put forward special controls which contain new requirements to improve safety for pediatric medical cribs and medical bassinets,
- Change the name of the device classification regulation from “pediatric hospital bed” to “pediatric medical crib,” and remove all other beds under the pediatric hospital bed classification to other classification regulations that are also class II, 510(k) exempt. For instance, FDA intends to move the following medical devices listed under § 880.5140 to devices with similar intended uses and class II regulations: Pediatric cribs with integrated air mattresses to 21 CFR 890.5170, “Powered flotation therapy bed;” youth beds to either 21 CFR 880.5100, “AC powered adjustable hospital bed,” or 21 CFR 880.5120, “Manual adjustable hospital bed,” depending on whether they are powered or not; pediatric stretchers to 21 CFR 880.6910, “Wheeled stretchers;” and crib enclosure beds to 21 CFR 880.6760, “Protective restraint.” This action would not have any substantive effect on the current marketing status of the devices.
- Move medical bassinets from “pediatric hospital beds” to its own device classification regulation (still as class II, 510(k) exempt), and
- Allow health care providers to prescribe use of pediatric medical cribs for pediatric patients outside of traditional health care settings.

Q2. What devices are affected by this proposed rule?

A2. Pediatric medical cribs and medical bassinets intended for medical purposes are regulated by the FDA (currently under 21 CFR 880.5140). These devices are class II, 510(k) exempt. Medical cribs and some

bassinets are under product code FMS, while product code NZG is exclusively for bassinets. This rule proposes to create a separate classification regulation for medical bassinets. If this rule is finalized, these bassinets will all be under product code NZG.

Q3. What is a pediatric medical crib?

A3. A pediatric medical crib is an open crib designed with fixed or moveable bed end rails and movable and latchable side rail components and a mattress designed to fit the crib. These cribs are typically used in hospital nurseries, labor and delivery units, patient rooms, or other health care settings.



Examples of pediatric medical cribs: _____



Q4. What is a medical bassinet?

A4. A medical bassinet is a small bed typically used in a hospital nursery, labor and delivery unit, patient room, or other health care settings for the individual care of a newborn baby, generally from birth to 3 months of age.

- A medical bassinet is a non-powered device that consists of two components: (1) a plastic basket or bed unit and (2) a durable frame with wheels, which holds the basket or bed component.
- The basket or bed component is a box-like structure generally made of a clear, high impact resistant, plastic material with an open top and four stationary walls to hold the baby.
- The frame may include drawers, shelving or cabinetry that provides space to hold baby care items.
- The casters (wheels) allow the bassinet to transport the baby throughout the care setting.

Examples of pediatric medical bassinets:



Q5. How many medical crib and medical bassinet manufacturers are registered with the FDA?

A5. As of September 1, 2015, there are 38 establishments associated with cribs, bassinets, and pediatric beds. There are 18 establishments in the FDA/CDRH Registration and Listing Database associated with the product code FMS and 20 establishments associated with product code NZG.

Q6. What actions has the Consumer Product Safety Commission taken on consumer cribs?

A6. On Dec. 28, 2010, the Consumer Product Safety Commission (CPSC) issued a final rule in the Federal Register establishing new standards for full-size and non-full-size cribs, which, among other things, prohibited drop-side rail designs. This rule became effective on June 28, 2011, for consumer household products and on

Dec. 28, 2012, for child care facilities, family child care homes, and places of public accommodation (e.g., hotels and motels).

- The CPSC rule bans the making or selling of drop-side rail cribs for non-medical purposes, strengthens crib slats (the vertical bars) and mattress supports, improve the quality of hardware, and require more careful testing of cribs for consumer use.
- The drop-side rail design was eliminated due to a number of infant deaths that occurred when the side rail of a consumer crib detached or disengaged.

Q7. What is the connection between the CPSC’s rule and the FDA’s proposed rule?

A7. CPSC's crib rule took effect for child care facilities/family child care homes in December 2012. Because drop-side rails are extremely helpful for patient care inside and outside of traditional healthcare settings, FDA's proposed rule is being issued to clarify that pediatric cribs for medical purposes can have the drop-side rail design and be used outside of traditional health care settings with a prescription.

In addition, FDA is proposing special controls which would impose safety requirements that align the requirements for cribs for medical purposes to ensure that these devices are used safely and effectively in both traditional and non-traditional health care setting. These special controls include establishing standards for the spacing between crib slats, strength of crib slats and mattress supports, the quality of the hardware and the testing of cribs.

Pediatric medical cribs and medical bassinets are medical devices regulated by the FDA because they are intended for use in the treatment of infants and children. Pediatric medical cribs may have head or foot ends or side rails that drop down so health care providers have easy access to the patient. Pediatric medical cribs and medical bassinets allow health care providers to:

- Access patients easily to provide emergency and routine daily care needs;
- Access patients to perform medical procedures and interventions;
- Reduce caregiver back injuries;
- Allow for the placement of certain specialized medical equipment; and
- Transport patients easily.

For pediatric medical cribs, the drop-side rail design is important because it provides caregivers ready access to the infant or child. The CPSC crib standards prohibiting drop-side rail designs for cribs do not apply to pediatric medical cribs (effective June 2011 for consumers and December 2012 for manufacturers).

- The FDA regulates manufacturers of pediatric medical cribs and medical bassinets, while local and state child care licensing agencies are primarily responsible for child care facilities and family child care homes.

Note: Reference to ASTM standards is in the preamble of the proposed rule.

Q8. What adverse event reports are associated with pediatric medical cribs and medical bassinets?

A8.

Adverse Event Reports Associated with Open Pediatric Medical Cribs and Bassinets January 1, 2005 – September 1, 2015 (n=556)		
Type of Events Associated with Reports	Serious Injury	15
	Malfunction	501

Type of Pediatric Bed Associated with Reports	Open Cribs	516
	Bassinets	40

Note: Open and enclosed hospital beds were originally cleared under one product code, FMS. However, in 2011, enclosed hospital beds were classified as a protective restraint under a separate product code, OYS, and no longer categorized under the hospital bed classification regulation. The chart above only includes open cribs and bassinets.

From January 1, 2005 to September 1, 2015, there were 556 adverse events associated with open pediatric medical cribs and bassinets.

304 adverse event reports were specifically associated with failure of the drop-side rail or access door within side rail to remain latched.

- **299** events resulted in no injury to the patient or healthcare professional.
- **3** events resulted in a head injury to a child.
- **2** events resulted in an arm injury to a nurse.

Device Problems associated with the use of open pediatric medical cribs include:

- side rail drop, cause unknown,
- side rail drop due to cable break,
- side rail not lowering,
- brakes not locking/holding,
- wheel broken,
- handle release not working,
- scales not reading correct weights, and
- cracked/peeled paint coating on rails leaving sharp edges.

Device Problems associated with the use of medical bassinets include:

- shelf support bracket failure,
- wheel broken,
- chart hook cracks,
- sharp, brittle edges on plastic tub, and
- knob detached.

Injuries associated with the use of open pediatric medical cribs include:

- entrapment of head (1 report) or extremities caught between rails (6 reports)
- unspecified head injury (1 report) due to side rail drop,
- unspecified arm injury to nurse (2) due to side rail drop
- unspecified back injury to nurse (1) due to side rail not lowering
- bone fractures - skull fracture (2); leg fracture (1) from side rail drop, and
- head injury from fall where no device problem was found (1).

There were no injuries associated with the use of medical bassinets.

Q9. What does FDA recommend consumers do?

A9. If this rule is finalized, parents should evaluate the risks and benefits of using a pediatric medical crib in their private home and discuss whether this is medically necessary with their child’s health care provider. If

they are aware that a child who will be using the facility has a prescription for a pediatric medical crib and will be using such crib in the facility, child care facilities, and places of public accommodation should check with state or local inspection agencies for information regarding training, inspection requirements, or other concerns related to the use of pediatric medical cribs outside of traditional health care facilities.

Q10. What do you recommend health care professionals do?

A10. If this rule is finalized, health care providers should educate parents who are staying with their child in a medical facility or who have a prescription to use a medical crib in their home about the expected performance of pediatric medical cribs and the safe use of movable and latchable side rails on medical cribs. For non prescription use of medical cribs, hospital staff should follow the manufacturer’s instructions for care and use of pediatric medical cribs and medical bassinets located in their facilities.

Q11. Why are medical facilities, such as hospitals, allowed to keep medical cribs with drop-side rails?

A11. Pediatric medical cribs are medical devices regulated by the FDA and are not required to comply with CPSC crib standards, which have numerous safety-enhancing requirements, including a ban of traditional drop-side rail designs for cribs.

Drop-side rails are a necessary feature of pediatric medical cribs because they ensure that caregivers have ready access to children and infants receiving medical care. They allow medical staff to perform CPR and other life-saving procedures quickly, and to perform many other tasks easily such as drawing blood, inserting intravenous therapy, providing respiratory care, wound care, and daily care. Drop-side rails also help prevent back and other injuries to medical staff that are caused by frequently reaching over fixed side rails while lifting pediatric patients in and out of the crib. The majority of MDRs for medical cribs were for malfunctions such as drop-side rails not latching or lowering, brakes not holding, wheels or casters breaking, and where applicable, scales not reading correct weights. These malfunctions were not associated with any adverse health effects or as serious as injuries from consumer drop-side cribs because of the extensive monitoring and training by medical staff in hospitals.

Q12. What measures is the FDA proposing to help prevent risks with pediatric medical cribs?

A12.

Health Risks and Mitigation Measures for Pediatric Medical Crib

Identified Risks	Mitigation Measures
Entrapment, Falls and Strangulation	Performance Testing Rail and End Panel Design Side Rail Spacing and Safety Features Appropriate Fitting of Mattress Pad
Injury Resulting from Mechanical or Structural Failure of the Device	Performance Testing Design Testing
Pinching, Lacerations, Splinters and Foreign Body Ingestion	Appropriate Materials Free from Surface Defects Labeling
Burns	CPSC’s Mattress Flammability Standard
Use Error	Labeling

Q13. What measures is the FDA proposing to help prevent risks with medical bassinets?

A13.

Health Risks and Mitigation Measures for Medical Bassinet

Identified Risks	Mitigation Measures
Crazing or Cracking of Basket or Bed Component	Performance Testing Labeling
Burns	CPSC's Mattress Flammability Standard
Injury Resulting from Mechanical or Structural Failure of the Device	Performance Testing Labeling
Use Error	Labeling

Q14. When are comments on the proposed rule due?

A14. The FDA will take comments on the proposed rule for 60 days after the date of publication in the Federal Register.

Q15. What is the difference between cribs and bassinets for non-medical purposes and pediatric medical cribs and medical bassinets for medical purposes?

A15. Pediatric medical cribs and medical bassinets are medical devices regulated by the FDA. These devices are not required to comply with CPSC's crib standards, which, among other things, prohibit drop-side rail designs for cribs. Currently, pediatric medical cribs can have drop-side rails and this proposed rule proposes to continue to allow drop-side rails for pediatric medical cribs. Drop-side rails are important for providing safe medical care, while cribs for non-medical purposes are banned from having drop-side rails due to a number of infant deaths that occurred when the side rail of such cribs separated or disconnected.

Unlike cribs and bassinets for non-medical purposes, pediatric medical cribs and medical bassinets are typically made of more durable materials and monitored and cared for by professional hospital staff, and thus, FDA has not received adverse event reports about infant deaths caused by the drop-side rail design. Nonetheless, to reduce the chance of harm to infants and children caused by entrapment (when a patient is caught, trapped, or entangled in or about the bed rail, mattress, or bed frame), strangulation (choking), or fire, FDA is proposing to establish special controls for pediatric medical cribs and medical bassinets.

Q16. How do I find out if my crib or bassinet is a medical crib or bassinet?

A16. To identify pediatric medical crib and medical bassinet manufacturers registered with the FDA, visit the FDA's Registration and Device listing data base at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm>.

Once on the homepage, you should click on "Search Registration and Listing" and then click on "Search Registration and Listing database" to access the public registration and listing database. The public registration and listing database contains registration and listing information for manufacturers whose registration is active and up-to-date for the year. All manufacturers of medical devices are required to register and list their devices. Using the search button, enter the product code (FMS) for the pediatric medical cribs and bassinets in the appropriate field. Doing this filter provides a list of active and up-to-date manufacturers of pediatric cribs and bassinets.

Q17. Why has it taken so long for FDA to issue this proposed rule when the Consumer Product Safety Commission issued their final rule for consumer cribs in 2010?

A17. Although the CPSC rule was finalized in 2010, the rule prohibited the use of the drop-side rail design for non-medical cribs in consumer households as of June 28, 2011. This rule did not affect pediatric medical cribs regulated by FDA, which may contain a drop-side rail design that includes movable and latchable side and end rails. However, the FDA has been conducting a full review of the best available data, including obtaining information from pediatric wards of MedSun hospitals and daycare centers.

In addition, the FDA wanted to ensure that all the available information on recent medical device adverse event reports on pediatric medical cribs and medical bassinets was included to determine the most appropriate special controls to mitigate any risks. We carefully evaluated the comments we received from stakeholders along with other available data to achieve an appropriate regulatory balance in this proposed rule.

Q18. Why is this proposed rule needed if companies have already created safety measures to address risks to pediatric patients ? Is the FDA behind on this issue ?

A18. The FDA does not know for certain that all manufacturers currently comply with the proposed safety requirements (i.e., special controls) proposed in the rule. In order to provide reasonable assurance of safety and effectiveness by mitigating the risks associated with pediatric medical cribs and medical bassinets, FDA must require that manufacturers comply with these special controls.

Q19. Are pediatric medical cribs and bassinets in use right now unsafe since they are not yet required to adhere to the proposed safety requirements ?

A19. No. FDA is proposing to revise the identification in § 880.5140 to only include pediatric medical cribs and to establish special controls for this device and to separate the identification and special controls for medical bassinets. The Agency is taking these actions to clarify the devices and establish special controls the Agency believes are necessary for a reasonable assurance of safety and effectiveness.

Q20. Once the proposed rule is finalized, will hospitals be required to replace their existing pediatric medical cribs and bassinets with new ones that meet the new standards ?

A20. No. Once this rule is finalized, it will not be retroactive ;therefore, FDA is not requiring devices currently on the market to be removed.

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