



FDA issues new rule on pediatric medical cribs, medical bassinets

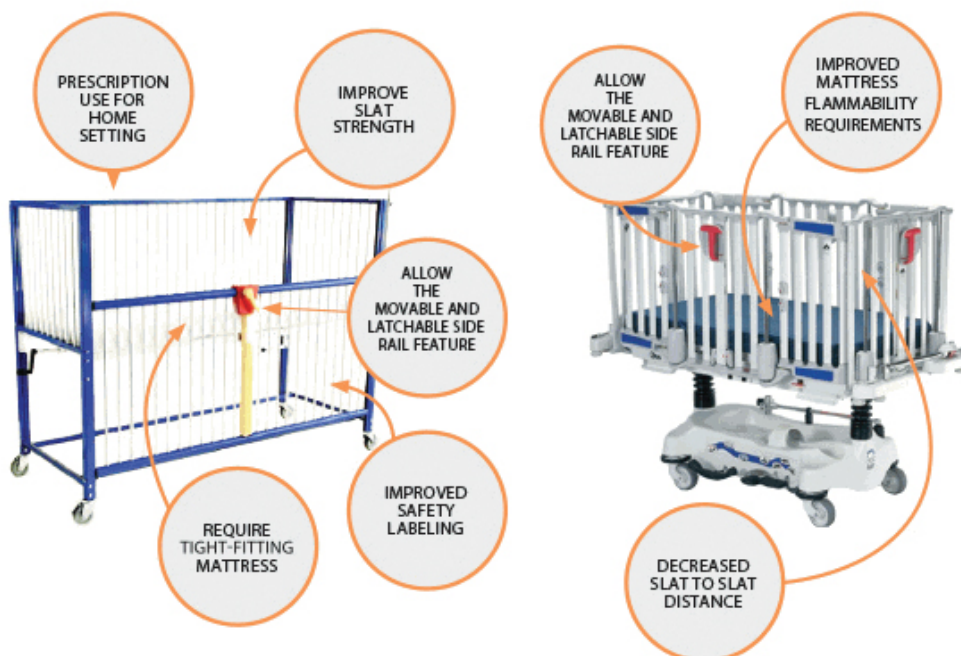
by from the Food and Drug Administration Office of Pediatric Therapeutics, Division of Pediatric and Maternal Health, and Center for Devices and Radiological Health

The Food and Drug Administration (FDA) published a final rule on Dec. 19, 2016, that provides guidance on using pediatric medical cribs and medical bassinets outside the health care setting and addresses risks associated with these devices.

The new rule allows pediatric medical cribs with drop-side or latched rails and medical bassinets to be used in a home, child care center or other facility if prescribed by a health care provider for a particular patient. The FDA requirements will provide reasonable assurance that pediatric medical cribs and medical bassinets are safe and effective.

In 2011, the Consumer Product Safety Commission (CPSC) banned cribs with drop-side rails for use in homes due to infants falling out of the cribs and getting limbs caught between slats. The ban was extended to cribs used in child care centers and facilities such as hotels in 2012.

FDA regulation has allowed pediatric medical cribs *used in health care settings* to have drop-side rails to make it easier to provide medical care to sick children. The new rule expands the settings in which medical cribs with side rails may be used.



Examples of Pediatric Medical Cribs and Proposed Special Controls



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The final rule will:

- provide, when it is medically necessary, continued access by prescription to pediatric medical cribs with drop-side rails in a home, child care or other facility;
- further reduce potential risks associated with pediatric medical cribs and medical bassinets, such as entrapment or fire;
- require warning labels for both pediatric medical cribs and medical bassinets to reduce risks of injuries; and
- convey the FDA's safety expectations and requirements by providing manufacturers with more specific design requirements for pediatric medical cribs and medical bassinets.

The rule specifies that manufacturers conduct design and performance testing to reduce risks 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, and injuries caused by compromised surface material.

The requirements address risks associated with medical bassinets, such as tipping of the device and cracks in the plastic material, which may result in injuries (e.g., bruises, burns and cuts).

The rule specifies that mattresses intended for use with pediatric medical cribs are required to meet CPSC mattress flammability standards.

Resource

- [More information on the use of pediatric medical cribs and bassinets](#)