CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1222

[Docket No. CPSC–2012–0067]

Safety Standard for Bedside Sleepers

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is proposing a safety standard for bedside sleepers in response to the direction under Section 104(b) of the CPSIA.

DATES: Submit comments by February 25, 2013.

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature of the proposed rule should be directed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202–395–6974, or emailed to oira_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC–2012–0067, may be submitted electronically or in writing: Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: http://www.regulations.gov.

Supplementary Information: A. Background and Statutory Authority

The Consumer Product Safety Improvement Act of 2008 (CPSIA, Pub. L. 110–314), was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission to: (1) Examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts, and (2) promulgate consumer product safety standards for durable infant and toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further
reduce the risk of injury associated with the product. The term “durable infant or toddler product” is defined in section 104(f)(1) of the CPSIA as a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years.

In this document, the Commission is proposing a safety standard for bedside sleepers. Bassinets and cradles are specifically identified in section 104(f)(2)(L) as durable infant or toddler products. Bedside sleepers are similar to bassinets, and many bedside sleepers also function as bassinets. In addition, some bedside sleepers are accessories to play yards/non-full-size baby cribs. On October 3, 2012, the Commission approved a notice of proposed rulemaking (NPR) for a Safety Standard for Bassinets and Cradles (http://www.cpsc.gov/library/foia/foia12/brief/bassinetsnpr.pdf). The Commission has issued a Safety Standard for Play Yards, codified at 16 CFR part 1221. Recently the Commission has proposed specific language to address hazards due to disassembly at play yard bassinet accessories in a notice of proposed rulemaking (77 FR 52272, August 29, 2012). This proposed rule, if finalized, would amend the Safety Standard for Play Yards. The proposed rule for bedside sleepers would adopt many of the requirements in the proposed NPR for bassinets, as well as address the hazards associated with the use of bassinet play yard accessories that can be assembled with missing key structural requirements for bedside sleeper play yard accessories.

Pursuant to Section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public in the development of this proposed standard, largely through the ASTM process. The proposed standard is based on the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F2906–12, “Standard Consumer Safety Specification for Bedside Sleepers” (ASTM F2906–12), with additions to make the standard more stringent. The ASTM standard is copyrighted, but it can be viewed as a read-only document, only during the comment period on this proposal, at: http://www.astm.org/cpsc.htm, by permission of ASTM.

B. The Product

ASTM F2906–12 defines “bedside sleeper” as “a rigid frame assembly that may be combined with a fabric or mesh assembly, or both, used to function as sides, ends, or floor or a combination thereof, and that is intended to provide a sleeping environment for infants and is secured to an adult bed.” A “multi-mode product” is “a unit that is designed and intended to be used in more than one mode (for example, a play yard, bassinet, changing table, hand held carrier, or bedside sleeper).” A bedside sleeper is intended to be secured to an adult bed that permits newborns and infants to sleep close by an adult without being in the adult bed. In current products, the horizontal sleep surface is typically 1 inch to 4 inches below the level of the adult bed’s mattress. The side of the bedside sleeper that is adjacent to the adult bed can usually be lowered, thereby differentiating bedside sleepers from bassinets, where all four sides of a bassinet are the same height. Bedside sleepers are intended for use with children up to the developmental stage where they can push up on hands and knees (about 5 months). This is the same developmental range for the intended users of bassinets. Current bedside sleepers range in size from about 35” x 20” to 40” x 30.” They may have rigid sides, but they are most commonly constructed with a tube frame covered by mesh or fabric.

Freestanding bassinets are not covered under the proposed standard for bedside sleepers. They are covered under ASTM F2194–12a, “Standard Consumer Safety Specification for Bassinets and Cradles.” Several manufacturers produce multiuse (or multimode) bedside sleeper products that convert into bassinets and/or play yards. Most bedside sleeper products can be converted into a bassinet by raising the lowered side to have four equal-height sides, and a few also convert into a bassinet and play yard. Some play yards include bedside sleeper accessories which, when attached, convert the play yard into a bedside sleeper; and some bassinets convert into bedside sleepers. All of the tube-framed products that have been evaluated by CPSC staff may be collapsed for storage and transport. A bedside sleeper that can be used in additional modes would need to meet each applicable standard. For example, a bedside sleeper product that converts into a play yard and a bassinet would have to meet: ASTM F2906 bedside sleeper requirements, ASTM F2194 bassinet requirements (except for height of the fourth lowered side for bedside sleepers) and sections of the ASTM F406 play yard requirements applicable to bassinet use in the bedside sleeper mode; ASTM F406 play yard requirements when in play yard use mode; and ASTM F2194 bassinet requirements and applicable sections of ASTM F406 play yard requirements when in bassinet mode.

To ensure consistency with the existing and proposed standards for bassinets and play yards, the Commission is proposing additions to the scope and performance requirements of a bedside sleeper, as discussed below.

C. The Voluntary Standard—ASTM F2906

ASTM first published a voluntary standard for bedside sleepers, ASTM F2906–11, in December 2011. It required bedside sleepers to meet the voluntary standard requirements of the product upon which it was based, either a play yard/non-full-size baby cribs, ASTM F406 (play yard standard) or a bassinet, ASTM F2194 (bassinet standard). The standard also addressed hazards specific to bedside sleeper products. It addressed incidents involving the creation of a hazardous gap between the product and an adult mattress, by requiring the successful completion of three disengagement tests. The tests ensured that the securing components can withstand forces that may be exerted on the product by either the child or an adult, while sleeping. The gap must be no more than 0.5 in. when the product is installed to the adult bed, per manufacturer’s directions. When a 25-lb. horizontal force is applied near the attachment system or corners, the gap may not exceed 1.0 in. And, to simulate an adult rolling into a bedside sleeper while sleeping, a gap greater than 1.0 in. may not be created after the application and release of a 50-lb. horizontal force to the bedside sleeper’s corners. The inclusion of these anti-gap requirements served to mitigate the foreseeable head and neck entrapment hazards posed by bedside sleepers. The standard requires a minimum 4-inch lowered side height over which a child is unlikely to be able to roll. In addition, latching and locking devices are evaluated to prevent unintentional movement of the side that lowers and to ensure overall product integrity.

In 2012, the standard for bedside sleepers was changed from meeting either ASTM F406 (play yard standard) or ASTM F2194 (bassinet standard), to require all products to meet ASTM F2194 only. The bassinet minimum side-height requirement (the upper surface of the non-compressed mattress of a bassinet/cradle must be at least 7.5 inches lower than the upper surface of the lowest side in all intended bassinet/cradle use positions) is also required for
beside sleepers, with the exception of a lowered side rail (the height of the side rail in the lowest position shall be no less than 4 inches when measured from the top of the uncompressed bedside sleeper mattress to the top of the lowered side rail, when the mattress support is in its highest position.) Bedside sleepers and bassinets share a significant number of hazard patterns because they are used by children with the same developmental abilities and for the same purpose. Many bedside sleepers also function as bassinets. By requiring bedside sleepers to be tested to ASTM F2194 (bassinets) rather than to ASTM F406 (play yards), ASTM made the bedside sleeper standard more stringent because there are bedside sleeper hazards covered by the bassinet standard but that are not covered by the play yard standard. Additionally, ASTM F406 requires a bassinet accessory on a play yard structure to meet the applicable sections of the play yard voluntary standard. These changes were incorporated into ASTM F2906–12, “Standard Consumer Safety Specification for Bedside Sleepers,” in July 2012.

CPSC staff also reviewed mandatory and voluntary international standards in Canada, the European Union, Australia, and New Zealand. There are some international standards governing safe sleep products for infants; however, there are no specific requirements that address the hazards unique to bedside sleeper products. Canada has a mandatory standard for cribs, cradles, and bassinets, SOR/2010–26; the European Union uses EN 12790 Child Care Articles—Reclined Cradles to assess and market various design elements and structures in bedside sleeper products. In Australia and New Zealand, several standards exist for safe sleep products—AS/NZS 2172:2003 Cots (full-size and non-full-size cribs that do not fold); AS/NZS 2195:1999 Folding Cots (play yards and folding cribs of any size); AS/NZS 4385:1996 Infants’ Rocking Cradles (cradles and bassinets that tilt.)

The Juvenile Products Manufacturers Association (JPMA) has a certification program for a variety of juvenile products, including bassinets and play yards. Manufacturers that voluntarily obtain JPMA certification submit products to an independent test laboratory for conformance testing to the most recent version of the voluntary standard. Manufacturers have 6 months after publication of a new or revised standard to certify products to the new requirements. Currently, JPMA does not have a certification program for bedside sleepers, and no firm claims to meet the ASTM voluntary standard, ASTM F2906–12. However, three firms supply multimode products, where one mode is compliant with the associated ASTM voluntary standard. Two firms claim compliance with the ASTM standard for bassinets; one firm is JPMA-certified as compliant, and the other claims compliance with the ASTM bassinet standard. A third firm supplies play yards that are JPMA-certified as compliant with the ASTM play yard/ non-full-size crib standard.

D. Incident Data

CPSC staff identified 40 cases of bedside sleeper-related incidents from 2001 to 2011. The CPSC databases searched were the In-Depth Investigation database, the Injury or Potential Injury Incident database, and the Death Certificate file. National estimates of bedside sleeper product-related injuries are not available because the National Electronic Injury Surveillance System (NEISS) data does not allow for clear identification of bedside sleepers. Therefore, the risk of injury associated with the number of products in use cannot be calculated.

CPSC staff is aware of four fatalities and 36 nonfatal incidents (with and without injuries) related to bedside sleepers that were reported from January 2001 through December 2011. Bedside sleepers have been on the market since 1997. During this time, there have been two recalls for product defects that created a substantial product hazard. One recall involved four deaths, three from head entrapment and one from suffocation, and several complaints on the same entrapment hazard from a bedside sleeper with a bassinet base. This recall involved 3-in-1 and 4-in-1 convertible bassinets that contained metal bars covered by an adjustable fabric flap, attached with Velcro® that folded down when the bassinet was converted into a bedside sleeper. If the Velcro® was not resecured properly when the flap was adjusted, an infant could slip through the opening and become entrapped in the metal bars and suffocate. Because of additional incidents, this recall was re-announced three times. There were 900,000 units recalled. The second recall involved a bedside sleeper with a play yard base. There were 10 reports of infants falling from the mattress into the bottom of a bedside sleeper or becoming entrapped between the edge of the mattress and the side of the bedside sleeper. There were 76,000 units recalled. Details of the recalls can be found on the cpsc.gov Web site.

1. Fatalities

All four reported fatalities involved the same brand of recalled bedside sleeper/bassinet. In all four cases, the product was being used in the bassinet mode, with the adjustable side raised at the time of the incident. Three of the deaths were due to entrapment and/or hanging, which resulted after an infant’s body, but not head, slipped through the fabric covering and underlying structural components of a particular brand of bedside sleeper. In two of these three fatalities involving a 4-month-old and a 6-month-old decedent, the infant’s head was entrapped between the lower horizontal bars (of the adjustable side) and the top of the mattress. The fabric flap designed to cover the metal bars was not in place. In the third fatality, the fabric flap covering the adjustable side was not secured to the permanent fabric siding, and the horizontal bars of the adjustable side were broken/missing. As a result, the 6-month-old decedent’s body slipped out through an opening in the fabric siding; but her chin/throat got caught on a lower crossbar. The fourth death occurred when an infant moved into a corner where the fabric covering the adjustable side was not secured by the Velcro® strip and the bassinet was also missing the lower rail. This created a pocket between the side and bassinet floor. The infant was found with their head in the pocket and face against the side of the bassinet, resulting in suffocation.

2. Nonfatal Incidents

Of the 36 nonfatal incidents, there were three reported injuries involving infants, none hospitalized, during the use of a bedside sleeper. All of the injured infants were under 5 months of age, which is within the ASTM recommended user age range. Two of the infants suffered bruising when they were entrapped between the metal rungs of the same product that had caused three of the fatalities described in the previous section. The third injury occurred when the infant rolled into a position where his neck was hypereextended into a non-breathable corner of the product, and he suffered respiratory difficulties. In all three cases, the caregiver was nearby to prevent any serious consequences.

The remaining 33 reports indicated that no injury occurred or provided no information about any injury. However, many of the descriptions in the reports indicated the potential for a serious injury, or even death, in bedside sleepers. In cases where victim age was reported, six reported ages between 6
months and 8 months old; the other infants were under 5 months of age.

3. Hazard Pattern Analysis

CPSC staff considered all 40 incident reports to identify the hazard patterns associated with bedside sleeper-related incidents. The hazard scenarios in 24 of the 40 incidents (60 percent) reported were attributed to some sort of failure/defect or a potential design flaw in the product. This category includes the four fatalities and three non-hospitalized injuries. Listed below are the reported problems, beginning with the most frequently reported concerns:

- A problem with the adjustable fabric cover over the horizontal metal bars on the side that lowers in the bedside sleeper mode was responsible for nine of the reported incidents. These included all four fatalities and two of the injuries. All of these incidents involved one particular manufacturer’s bedside sleeper/convertible bassinet product, which was recalled in 2008. Two of the fatalities occurred before the CPSC recall; the third, which involved a secondhand product in poor condition, occurred after the 2008 recall, but prior to the 2009 recall (which was an expansion of the 2008 recall). Between the two injuries, one occurred prior to the 2008 recall, while the other occurred after that recall. Neither of the post-recall incident reports indicated whether the consumers were aware of the recall.

- Issues with assembly instructions were identified in six reported incidents. In all of these reports, the consumer had misassembled the product but reported the product as being faulty. None of the incidents resulted in any injury or fatality. All but one of these incidents involved one particular manufacturer’s bedside sleeper, which was recalled in 2011.

- Miscellaneous other product-related issues, such as non-levelness of the product (two reports), instability of leg extensions (two reports), poor design (two reports), broken component (one report), failure of the attachment (to adult bed) mechanism (one report), and unclear age labeling (one report) were reported in the remaining incident reports. One incident reported an injury associated with poor product design.

- In response to CPSC recall notices, there were 16 non-incident reports of concerns or complaints. In these reports, the consumer either sought advice on options regarding a bedside sleeper product they owned that had been recalled, or they inquired about whether the product they owned was within the scope of the recall.

E. Proposed Changes to ASTM F2906–12

CPSC staff identified 24 incidents due to defect or potential design flaws in the product. The hazards associated with these incidents included: issues with the adjustable fabric cover over the metal bars on the side that lowered in the bedside sleeper mode (9 incidents); poor assembly instruction (6 incidents); and miscellaneous other product-related issues (9 incidents). To address these incidents, the Commission proposes to adopt by reference, ASTM International’s voluntary standard, ASTM F2906–12, Standard Consumer Safety Specification for Bedside Sleepers, with a few additions to strengthen the standard. Section 5 (Performance Requirements) of ASTM F2906–12 requires that in addition to the tests provided in ASTM F2906–12, the bedside sleeper must be tested to the bassinet standard (ASTM F2194). Specifically, section 5.1 provides that:

Prior to or immediately after testing to this consumer safety specification, the bedside sleeper must be tested to Consumer Safety Specification F2194. Multi-mode products must also be tested to each applicable standard. When testing to Consumer Safety Specification F2194 the unit shall be free standing, and not be secured to the test platform as dictated elsewhere in this standard.

Because bedside sleepers already are required to be tested to the applicable bassinet standard requirements, and multimode products, to each applicable standard, the Commission proposes in this rule to add clarifying language to ensure that the requirements that are not yet included in an existing standard or proposed in an NPR (i.e., ASTM F406–12a (play yards) and ASTM F2194–12 (bassinets)) are also included in ASTM F2906–12 (bedside sleepers).

1. Fabric-Sided Enclosed Openings

The current version of ASTM F2194–12a (bassinets) contains a Fabric-Sided Enclosed Openings’ performance requirement for bassinets. This requirement prohibits completely bounded openings large enough to permit passage of an infant’s torso. The hazard scenarios addressed by this requirement encompass the three strangulation deaths described above and a related, foreseeable suffocation hazard. These hazards occur when a child passes through an opening, either becomes trapped between the liner and mattress pad and suffocates, or becomes suspended by the neck, and then strangles. This hazard, associated with a recall of over three of the four fatalities on a bassinet that converts to a bedside sleeper. The bassinet test procedure (ASTM F2194–12a, section 7.8) attempts to push a torso probe the size of a 5th percentile infant through bounded openings with 20 lbs of force. The test is first performed with product assembled per the manufacturer’s instructions. If the product has a removable cover, it is performed a second time after all fasteners or snaps are unfastened, but the removable cover left in place. In doing so, the test intentionally replicates the incorrectly secured fabric liner hazard scenario of the fatal incidents.

A manufacturer’s bedside sleeper accessory exhibited this hazard, which led to its recall in 2011. The recall was initiated in response to incident reports in which the bedside sleeper accessory’s removable cover (liner or shell) was either not used, or was present but not secured to the play yard frame. This bedside sleeper accessory can also be used as a play yard, or a bassinet accessory to a play yard. When in the bassinet accessory position, the front side of the product can be lowered, transforming it into the bedside sleeper mode. A 1½ year-old unused sample of this product was recently retested by CPSC staff, confirming that it fails the ASTM F2194 fabric-sided enclosed opening requirement. However, a new sample of a similar model from the same manufacturer passed this test. Staff identified two possible reasons for testing variances. One explanation is that the fit of the shell to the play yard frame becomes looser with repeated assembly and disassembly. The other reason is that the seam joining the mesh and fabric part of the liner may be in a slightly different location on some models. The seam may cause sufficient friction on the torso test probe during force testing on some models. Accordingly, minor changes in materials or construction may not be sufficient to remedy the hazard presented by the fabric-sided, bounded opening hazard.

Under section 6.7 of ASTM F2194–12, for bassinets/cradles with fabric sides, a completely bounded opening may not be created that allows the complete passage of the torso probe (based on a torso diameter of a 5th percentile 0 to 2-month-old infant) when tested in accordance with the fabric release test methods for enclosed openings. However, the test does not apply to play yard bassinets or play yard accessories. Bassinets accessories to play yards (that cannot be converted to bedside sleepers) are usually held in place by fasteners that clip to the top of the play yard’s railing. If the fasteners were left unclipped, the bassinet would fall, rendering the product untestable, due to
the complete collapse of the bassinet attachment; test labs would likely consider that a failure. However, for bassinets that convert to a bedside sleeper with a lowered side, CPSC staff determined that all bedside sleeper play yard accessories should be subject to the requirements of the ASTM F2194–12 bassinet standard’s section 6.7 Fabric-Sided Enclosed Opening without the exemption for bassinet play yard accessories, given the demonstrated hazards presented when a bedside sleeper’s removable cover (liner or shell) is either not used, or not secured properly.

The Commission proposes additional language for the ASTM F2906 bedside sleeper standard to add a new definition for “bedside sleeper accessory” and eliminate the fabric-sided bounded opening performance requirement exemption currently granted to play yard bassinet accessories. Unlike bassinet play yard accessories, bedside sleeper (or a bassinet that is converted into a bedside sleeper) play yard accessories could have fasteners left unclipped (through the detachment of snaps/Velcro) where the bedside sleeper with the lowered side does not completely collapse. Because the bedside sleeper could still appear functional, the Commission proposes to add language under Section 3 (Terminology) of ASTM F2906–12. The new proposed section 3.1.8 would state: “bedside sleeper accessory, n—an elevated sleep surface that attaches to a non-full-size crib or play yard, designed to convert the product into a bedside sleeper intended to have a horizontal sleep surface while in a rest (non-rocking) position.” The Commission also proposes to add a new proposed section 5.7, stating: “a Bedside Sleeper Accessory Fabric-Sided Enclosed Openings—A bedside sleeper accessory shall meet the F2194 performance requirement “Fabric-Sided Enclosed Openings.” Under new proposed section 5.7.1, bedside sleeper accessories would be exempt from this requirement if either of the following two conditions were met after disengaging all fasteners between the accessory and the non-full-size crib or play yard base to which it is assembled: (1) The bedside sleeper accessory collapses under its own weight, such that any part of the mattress pad contacts the bottom floor of the non-full-size crib or play yard (5.7.1.1); or (2) the bedside sleeper accessory’s sleep surface tilts by more 30 degrees (5.7.2). These requirements are also consistent with the proposed requirements in the NPR for the Safety Standard for Play Yards for play yard bassinet accessory misassembly provisions, which require all key structural elements to be attached permanently to the bassinet shell. The second method of compliance is to meet a catastrophic failure test, where a missing key structural element makes the product collapse completely or tilt more than 30 degrees. 77 FR 52272.

2. Consumer Misassembly With Missing Components

The Commission proposed a requirement to address consumer misassembly of key structural elements for bassinet accessories to play yards in the NPR for the Safety Standard for Play Yards, 77 FR 52272. However, the NPR for play yards did not include specific language for bedside sleeper play yard accessories. Although section 5 (Performance Requirements) of ASTM 2906–12 provides that bedside sleepers must be tested to ASTM F2194 (bassinets), and multimode products must also be tested to each applicable standard, the Commission proposes to add language to ASTM 2906–12 (bedside sleepers) to make explicit that the requirements for addressing consumer misassembly of key structural elements is required for bedside sleeper play yard accessories in addition to bassinet play yard accessories.

As described at length in the NPR for the Safety Standard for Play Yards, 77 FR 52272, omission of key structural elements of a bassinet assembly (such as rods, tubes, bars, and hooks that keep the sleep surface flat and level) could result in a tilt in the sleeping surface and put the infant in a position where he or she is unable to breathe and is at risk of suffocation. This hazard is magnified should these misassembled products be used as an unsupervised sleep environment, another reasonably foreseeable scenario. Similarly, a misassembled bedside sleeper play yard accessory may not be readily apparent or obvious to the consumer. If the misassembled accessory supports an infant without a catastrophic and obvious change to the sleep surface, a consumer may continue to use the misassembled accessory and inadvertently place a child in danger. Bedside sleeper accessories and bassinet accessories incorporate very similar designs and manufacturing processes (because many bedside sleepers also function as bassinets), and many of the same performance requirements are applicable to both products. Accordingly, in order to ensure that all of the hazards associated with bedside sleeper play yard accessories and bassinet play yard accessories that can be assembled missing key structural elements are addressed, the Commission proposes to add under section 5 (Performance Requirements) to ASTM F2906–12, new proposed section 5.8 Bedside Sleeper Play Yard Accessories Missing Key Structural Elements. The new section 5.8 will provide: A bedside sleeper accessory shall meet the F406 general requirement, “Bassinet/Cradle Accessories Missing Key Structural Elements.”

3. New Requirements for Bassinets

ASTM F2906–12 already requires bedside sleepers to meet the requirements of the bassinet standard, ASTM F2194 “Standard Consumer Product Safety Specification for Bassinets and Cradles,” with the exception of the height of the lowered fourth side. Most bedside sleepers also function as bassinets. The intended users are identical, and the majority of the hazards are identical. The Commission’s proposed modifications to address bassinet hazards in ASTM F2194–12 have been discussed in great detail in the NPR and in the Bassinet NPR staff briefing package. Specifically, the Commission proposed four changes to the ASTM bassinet standard. Three of those proposed changes to the bassinet standard would also be applicable to bedside sleepers. The fourth proposed change would update the scope and corresponding terminology specific to bassinets under ASTM F2194, and it is not applicable to bedside sleepers.

Three of the proposed requirements that would apply to bedside sleepers include: (1) Segmented Mattress Flatness Requirement and Test Method; (2) Removable Bassinet Bed Stability; and (3) Stability Test Dummy. Because bedside sleepers are already required to be tested to the bassinet standard, ASTM F2194, there is no need to add language to the bedside sleeper standard proposing these requirements and test methods. Accordingly, if the proposed changes to ASTM F2194 are finalized, bedside sleepers will also be required to meet the following requirements and test methods in addition to all other applicable requirements in ASTM F2194. The following proposed changes to the bassinet standard would also be applicable to bedside sleepers:

A. Proposed Segmented Mattress Flatness Requirement and Test Method (Sections 6.9 and 7.10 of ASTM F2194–12a)

In order to address the hazard of suffocation/positional asphyxia due to excess mattress pad angle, the Commission proposed performance requirements and a test method for the
minimum flatness of mattress surfaces. This requirement would apply to segmented mattresses, such as those seen in a bassinet accessory to a play yard. The Commission proposed that the segmented mattresses commonly used in play yards shall not create an angle greater than 10 degrees when tested using a 17-pound cylinder to simulate the weight of a 6-month-old infant. This performance requirement and test method would also apply to a segmented mattress used in a bedside sleeper accessory to a play yard.

B. Proposed New Performance Requirement and Associated Definitions To Address Hazards Associated With the Stability of Removable Bassinet Beds (Sections 3.1.3, 3.1.17, 3.1.18, 3.1.19, 3.1.20, 6.10, 7.11 of ASTM F2194–12a)

In order to address hazards associated with misassembly of removable bassinet beds, the Commission proposed performance requirements and a test method for products that have bassinet beds that attach to an elevated stand. The requirements would apply to removable bassinet beds that are designed to separate from the stand/base without the use of tools. The Commission proposed that if a removable bassinet bed is not properly attached or assembled to its base, it must meet one of the following requirements:

- The base/stand shall not support the bassinet (i.e., the bassinet bed falls from the stand so that it is in contact with the floor); or
- The lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action); or
- The stand/base shall not be capable of supporting the bassinet bed within 20 degrees of horizontal; or
- The bassinet shall contain a visual indicator mechanism that shall be visible on both sides of the product; or
- The bassinet bed shall not tip over and shall retain the CAMI newborn dummy when subjected to the stability test outlined in the standard.

These requirements are equally applicable to removable bedside sleepers that are designed to separate from the stand/base without the use of tools.

C. Proposed Revised Test Procedure for Bassinet Stability (Sections 2.3 and 7.4.4 of ASTM F2194–12a)

During evaluations of the test methods for removable bassinet beds, CPSC staff made comparisons of the stability of products weighted with the newborn CAMI dummy (7.45 lbs) as opposed to the infant CAMI dummy (17.5 lbs). ASTM F 2194–12 contains a stability requirement that uses the heavier infant CAMI dummy. Use of the newborn CAMI, which is readily available to test labs and represents the 50th percentile newborn, would result in a more conservative stability test. In addition, bassinets are intended for use with newborns. Accordingly, the Commission proposed a revised test procedure for bassinet stability that uses a newborn CAMI instead of an infant CAMI. This test procedure is equally applicable to removable bedside sleepers that are designed to separate from the stand/base without the use of tools because they too are intended for use with newborns.

F. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of the rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). To allow time for bedside sleepers to come into compliance, the Commission proposes that the standard would become effective 6 months after publication of a final rule in the Federal Register. The Commission invites comment on how long it will take bedside sleeper manufacturers to come into compliance with the rule.

G. Regulatory Flexibility Act

1. Introduction

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires agencies to consider the impact of proposed rules on small entities, including small businesses. Section 603 of the RFA requires that the Commission prepare an initial regulatory flexibility analysis and make it available to the public for comment when the notice of proposed rulemaking is published. The initial regulatory flexibility analysis must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the initial regulatory flexibility analysis must contain:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- A description of the reasons why action by the agency is being considered;
- A succinct statement of the objectives of, and legal basis for, the proposed rule;
- A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
- An identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.

In addition, the initial regulatory flexibility analysis must contain a description of any significant alternatives to the proposed rule that would accomplish the stated objectives of the proposed rule and, at the same time, reduce the economic impact on small businesses.

2. The Market

Typically, bedside sleepers are produced and/or marketed by juvenile product manufacturers and distributors. Currently, there are at least five known manufacturers supplying bedside sleepers to the U.S. market. Four are domestic manufacturers, including one manufacturer that dominates the market. The fifth is a foreign manufacturer who ships products directly to the United States. There may be additional unknown small manufacturers and importers operating in the U.S. market as well.

Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of bedside sleepers is small if it has 500 or fewer employees, and an importer is considered small if it has 100 or fewer employees. Based on these guidelines, all four domestic manufacturers known to be supplying the U.S. market are small.

The Juvenile Products Manufacturers Association (JPMA), the major U.S. trade association that represents juvenile product manufacturers and importers, runs a voluntary Certification Program for several juvenile products. Under this program, products voluntarily submitted by manufacturers are tested against the appropriate ASTM standard, and only passing products are allowed to display JPMA’s Certification Seal.

Currently, JPMA does not have a Certification Program for bedside sleepers, and no firm claims to meet the ASTM bedside sleeper voluntary standard. However, three firms supply multimode products where one mode is compliant with the associated ASTM voluntary standard. Two firms claim compliance with the ASTM standard for bassinets; one firm is JPMA-certified as compliant, and the other claims compliance with the ASTM bassinet standard. A third firm supplies play yards that are JPMA-certified as compliant with the ASTM play yard/ non-full-size crib standard.
National estimates of bedside sleeper product-related injuries are not available because the National Electronic Injury Surveillance System (NEISS) data does not allow for clear identification of bedside sleepers. Therefore, the risk of injury associated with the number of products in use cannot be calculated.

3. Compliance Requirements of the Proposed Rule

Although all bedside sleepers currently on the market will require some modification in order to meet the voluntary standard, several of these requirements would impose little to no burden on manufacturers because firms also must comply with similar requirements in existing voluntary standards.

Several modifications of the product may be required. The lowered side of the bedside sleeper must be 4 inches. The height requirement for sides that cannot be lowered is identical to that of bassinets, 7½ inches. This requirement is not expected to pose a substantial cost for firms. However, it is possible that a few firms will need to modify their product in order to comply. Some products will need to add a permanent fourth side, and some may need to raise the fourth side so that it meets the minimum 4-inch side height.

ASTM F2906-12 requires that the gap between the bedside sleeper and adult bed should not be more than a ½ inch when the bedside sleeper is secured to the bed. Firms may need to modify the attachment system to meet the minimum requirement by adjusting the anchor and/or straps to reduce stretching and to limit slippage. Alternatively, firms may opt to redesign their attachment system. Cost should be minimal if no new materials are used.

Some products will require some modification in order to meet the two proposed bedside sleeper accessory requirements. The Commission proposes that the bedside sleeper accessory would be required to meet the (1) fabric sided opening requirement and (2) consumer misassembly requirement. In order to comply with the fabric opening requirement, the bedside sleeper accessory must pass the torso probe test. Alternatively, when the fabric-sided liner is unsecured, the bedside sleeper accessory should either collapse under its own weight or the sleep surface should tilt by more than 30 degrees. The proposed consumer misassembly requirement is identical to the play yard bassinet misassembly requirement proposed in the NPR for the Safety Standard for Play Yards. The Commission proposes that a bedside sleeper accessory that can be assembled and attached to the play yard with any of the key structural elements missing must either: (1) Have all key structural components permanently attached or (2) be obviously unusable when attached to the play yard with any key structural element removed. The bedside sleeper accessory, if misassembled, should provide visual cues, such as the mattress pad contacts the bottom floor of the non-full-size crib or play yard, or the sleep surface angle tilts by more than 30 degrees to indicate misassembly. The actual cost of meeting these proposed requirements to manufacturers is unknown, but it could be minimal, primarily involving additional stitching, rivets, and other methods of attachment. However, if product redesign is required, the costs could be significant.

The proposed bassinet requirements that are also applicable to bedside sleepers—mattress and stability requirements—are expected to have little to no incremental impact on firms. These requirements are identical to requirements in the bassinet NPR for Safety Standard for Bassinets and Cradles and the cost of meeting those requirements was accounted for in the bassinet NPR. If these requirements are finalized as proposed, a manufacturer who produces a bedside sleeper and a bassinet combination product would already need to meet these requirements and would have incurred the associated costs under the bassinet standard. As a consequence, meeting the same requirements on a bedside sleeper standard would impose no additional burden. Most bedside sleeper manufacturers produce such a combination product. In addition, firms would need to revise current warning labels to include a description of correct assembly and conversion modes. This represents a minor modification.

4. Other Federal or State Rules

The Commission is in the process of implementing sections 14(a)(2) and 14(i)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSA. Section 14(a)(2) of the CPSA requires every manufacturer of a children’s product that is subject to a children’s product safety rule to certify, based on third party testing, that the product complies with all applicable safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards (i) for ensuring that a children’s product is tested periodically and when there has been a material change to the product, (ii) for the testing of representative samples to ensure continued compliance, (iii) for verifying that a product tested by a conformity assessment body complies with applicable safety rules, and (iv) for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler.

Because bedside sleepers will be subject to a mandatory standard, they will also be subject to the third party testing requirements of section 14(a)(2) of the CPSA when the mandatory standard and the notice of requirements become effective.

5. Impact on Small Businesses

There are five firms known to be marketing bedside sleepers in the United States. One is a foreign manufacturer. The analysis applies to the four domestic firms, all of which are small. The impact of the standard on manufacturers depends on two factors: (1) Whether their products are multiuse products and are already in compliance with one or more existing voluntary (or mandatory) standards; and (2) the proportion of their total sales or revenue that bedside sleepers constitute.

Three of the four domestic manufacturers produce a multiuse product, or a product that may be used as a bedside sleeper, as well as a play yard or bassinet. These multiuse products are already in compliance with an existing standard, and there is significant overlap between standards. It is likely that manufacturers will need to make only slight, if any, modifications to comply with the bedside sleeper standard. The three producers of multiuse products are unlikely to experience a significant impact.

Two of the domestic manufacturers rely almost solely on the sales of bedside sleepers as their revenue source. One of the firms produces a multiuse product that is in compliance with an existing voluntary standard, as described above, and should not experience a significant impact. The other firm, however, produces a product that serves only as a bedside sleeper. The costs of compliance for this firm are unknown but could be significant if a complete product redesign is required. In addition, the impact could be magnified because most of this firm’s revenues are due to the sales of bedside sleepers.

All manufacturers will need to modify existing warning labels. A new warning label poses a small burden because it represents a minor modification. Costs associated with the new warning label would be low because no new materials are required. The costs of notice of requirements are in effect, all manufacturers will be subject to third
party testing and certification requirements.

6. Alternatives

Under the Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, one alternative that would reduce the impact on small entities is to make the voluntary standard mandatory with no modifications. Adopting the current voluntary standard without any changes potentially would reduce costs for manufacturers. Three of the four small manufacturers who are already compliant with a voluntary standard would have a reduced burden. However, all firms still require some product changes in order to meet the voluntary standard. Because the staff’s proposed changes add little to the overall burden, adopting the voluntary standard with no changes will not significantly offset the burden.

A second alternative would be to set an effective date later than the staff-recommended 6 months. This would allow suppliers additional time to modify and/or develop compliant bedside sleepers and spread the associated costs over a longer period of time.

H. Environmental Considerations

The Commission’s regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. If our rule has “little or no potential for affecting the human environment,” it will be categorically exempted from this requirement. 16 CFR 1021.5(c)(1). The proposed rule falls within the categorical exemption.

I. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

• A title for the collection of information;
• A summary of the collection of information;
• A brief description of the need for the information and the proposed use of the information;
• A description of the likely respondents and proposed frequency of response to the collection of information;
• An estimate of the burden that shall result from the collection of information; and
• Notice that comments may be submitted to the OMB.

Title: Safety Standard for Bedside Sleepers.

Description: The proposed rule would require each bedside sleeper to comply with ASTM F2906–12, Standard Consumer Safety Specification for Bedside Sleepers. Sections 7.1, 8.1, and 8.2 of ASTM F2906–12 contain requirements for marking, labeling, and instructional literature that are disclosure requirements, thus falling within the definition of “collections of information” at 5 CFR 1320.3(c). Section 7.1 of ASTM F2906–12 requires that all bedside sleeper products meet with the marking and labeling instructions of ASTM F2194, Standard Consumer Safety Specification for Bassinets and Cradles. Section 8.1 of ASTM F2194–12 requires:

• The name and the place of business (city, state, mailing address including Zip code) or telephone number of the manufacturer, importer distributor, or seller; and
• A code mark or other means that identifies the date (month and year as a minimum) of manufacture.

Section 8.1 of ASTM F2906–12 requires that all bedside sleeper products comply with the instructional literature requirements of ASTM F2194, Standard Consumer Safety Specification for Bassinets and Cradles. Section 9.1 of ASTM F2194–12a requires all firms supplying bedside sleepers to provide easy-to-read and understand instructions regarding assembly, maintenance, cleaning, operating, and adjustments, where applicable. Section 8 of ASTM F2906–12 also requires that the instructions cover correct assembly of product and use of attachment system, and conversion, as well as alert consumers that they should read all instructions and keep the instructions for future use. These requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. 3502(3).

Description of Respondents: Persons who manufacture or import bedside sleepers.

Estimated Burden: We estimate the burden of this collection of information as follows:

<table>
<thead>
<tr>
<th>Table 1—Estimated Annual Reporting Burden</th>
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<tr>
<td>16 CFR Section</td>
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<td>1222</td>
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Our estimates are based on the following:

There are five known firms supplying bedside sleepers to the U.S. market. All five firms are assumed to use labels on both their products and their packaging already, but they might need to make some modifications to their existing labels. The estimated time required to make these modifications is about 1 hour per model. Each of these firms supplies an average of two different models of bedside sleepers; therefore, the estimated burden hours associated with labels is 1 hour × 5 firms × 2 models per firm = 10 annual hours.

Sections 8.1 and 8.2 of ASTM F2906–12 require instructions to be supplied with the product. This is a practice that is customary with bedside sleepers. bedside sleepers are products that generally require some installation and maintenance instructions, and any products sold without such information would not be able to compete successfully with products that provide this information. Therefore, because the CPSC is unaware of bedside sleepers that: (a) Generally require some installation, but (b) lack any instructions to the user about such installation, there are no burden hours associated with the instruction requirement in sections 8.1 and 8.2 because any burden associated with supplying instructions with bedside sleepers would be “usual and customary” and not within the definition of “burden” under the OMB’s regulations.

We estimate that hourly compensation for the time required to create and update labels is $27.64 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” June 2012, Table 9, total compensation for all sales and office workers in goods-producing private industries: http://www.bls.gov/ncs/). Therefore, the estimated annual cost associated with the proposed requirements is $276 ($27.64 per hour × 10 hours = $276).

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C.
This proposed rule begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for bedside sleepers. We invite all interested
persons to submit comments on any aspect of the proposed rule. Comments should be submitted in accordance with the instructions in the ADDRESSES section at the beginning of this notice.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment bodies.

16 CFR Part 1222


For the reasons discussed in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

1. The authority citation for part 1112 continues to read as follows:


2. Amend Part 1112.15 by adding paragraph (b)(34) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule and/or test method?

* * * * *

(b) The CPSC has published previously, or in the cases of 16 CFR parts 1221, 1223, and 1224, and ASTM F 963–11 for the first time, the requirements for accreditation for third party conformity assessment bodies to assess conformity with the following CPSC rules and/or test methods:

* * * * *

(34) 16 CFR part 1222, Safety Standard for Bedside Sleepers.

3. Add part 1222 to read as follows:

PART 1222—SAFETY STANDARD FOR BEDSIDE SLEEPERS

Sec.

1222.1 Scope.

1222.2 Requirements for Bedside Sleepers.


§ 1222.1 Scope.

This part establishes a consumer product safety standard for bedside sleepers.

§ 1222.2 Requirements for Bedside Sleepers.

(a) Except as provided in paragraph (b) of this section, each bedside sleeper must comply with all applicable provisions of ASTM F2906–12, Standard Consumer Safety Specification for Bedside Sleepers, approved on June 1, 2012. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; http://www.astm.org/cpsc.htm. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/ibr_locations.html.

(b) Comply with the ASTM F2906–12 standard with the following additions:

(i) In addition to complying with section 3.1.7 of ASTM F2906–12, comply with the following:

(ii) Bedside sleeper accessory, n—an elevated sleep surface that attaches to a non-full-size crib or play yard, designed to convert the product into a bedside sleeper intended to have a horizontal sleep surface while in a rest (non-rocking) position.

(ii) [Reserved]

(2) In addition to complying with section 5.6 of ASTM F2906–12, comply with the following:

(i) Fabric-Sided Enclosed Openings—A bedside sleeper accessory shall meet the F2194 performance requirement, “Fabric-Sided Enclosed Openings.”

(A) 5.7.1 Bedside sleeper accessories are exempt from this requirement if either of the following two conditions is met after disengaging all fasteners between the accessory and the non-full-size crib or play yard base to which it is assembled:

(B) 5.7.1.1 The bedside sleeper accessory collapses under its own weight, such that any part of the mattress pad contacts the bottom floor of the non-full-size crib or play yard.

(C) 5.7.1.2 The bedside sleeper accessory’s sleep surface tilts by more than 30 degrees.

(ii) Bedside Sleeper Play Yard Accessories Missing Key Structural Elements: A bedside sleeper accessory shall meet the F406 general requirement

“Bassinet/Cradle Accessories Missing Key Structural Elements.”


Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2012–29583 Filed 12–7–12; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1225

[CPSC Docket No. CPSC–2012–0068]

RIN 3041–AD16

Safet Standard for Hand-Held Infant Carriers

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) requires the United States Consumer Product Safety Commission (Commission, CPSC, or we) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is proposing a safety standard for handheld infant carriers in response to the direction under Section 104(b) of the CPSIA. The proposed rule would incorporate ASTM F2050–12 by reference, with two modifications.

DATES: Submit comments by February 25, 2013.

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the marking, labeling, and instructional literature of the proposed rule should be directed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, Fax: 202–395–6974, or emailed to: oira_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC-2012-0068, may be submitted electronically or in writing:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: http://www.regulations.gov. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer...