United States
Consumer Product Safety Commission

This document has been electronically approved and signed.

Ballot Vote Sheet

TO: The Commission
Alberta E. Mills, Secretary

DATE: June 28, 2023

THROUGH: Austin C. Schlick, General Counsel
Jason K. Levine, Executive Director

FROM: Daniel R. Vice, Assistant General Counsel,
Regulatory Affairs
David M. DiMatteo, Attorney, Regulatory Affairs

SUBJECT: Final Rule: Safety Standard for Adult Portable Bed Rails

---

BALLOT VOTE DUE: Wednesday, July 5, 2023

Staff is forwarding to the Commission a briefing memorandum recommending that the Commission issue a final rule to address the risk of entrapment associated with adult portable bed rails. The Office of the General Counsel is providing for the Commission's consideration a draft final rule to do so pursuant to sections 7 and 9 of the Consumer Product Safety Act. The draft final rule establishes performance requirements for adult portable bed rails with a 30-day effective date following publication of the final rule in the *Federal Register*.

Please indicate your vote on the following options:

I. Approve publication of the final rule in the *Federal Register*, as drafted.

_____ _____
(Signature) (Date)

U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814

National Product Testing and Evaluation Center
5 Research Place
Rockville, MD 20850

II. Approve publication of the final rule in the *Federal Register*, with the specified changes.

_____

_____

_____

_____

_____ _____

(Signature) (Date)

III. Do not approve publication of the final rule in the *Federal Register.*

_____ _____

(Signature) (Date)

IV. Take other action specified below.

_____

_____

_____

_____

_____ _____

(Signature) (Date)

Attachment: Draft *Federal Register* notice "Final Rule: Safety Standard for Adult Portable Bed Rails"

U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814

National Product Testing and Evaluation Center
5 Research Place
Rockville, MD 20850

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1270

[CPSC Docket No. CPSC–2013-0022]

Safety Standard for Adult Portable Bed Rails

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule.

SUMMARY: The U.S. Consumer Product Safety Commission (Commission or CPSC) has determined that there is an unreasonable risk of injury and death associated with entrapment and other hazards from adult portable bed rails (APBRs). CPSC has identified 284 fatal incidents related to entrapment by APBRs between January 2003 and December 2021. To address the risk, the Commission is promulgating a rule under the Consumer Product Safety Act (CPSA) to require that APBRs meet the requirements of the existing voluntary standard for APBRs, with modifications. CPSC estimates that the final rule will provide up to $298 million per year in societal benefits, while the costs associated with the rule's requirements are expected to be approximately $2 million per year.

DATES: The rule is effective on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Will Cusey, Small Business Ombudsman, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7945 or (888) 531-9070; email: sbo@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

In 2013, the CPSC received two requests to initiate rulemaking proceedings under the Consumer Product Safety Act (CPSA) to address an unreasonable risk of injury associated with APBRs. Gloria Black, the National Consumer Voice for Quality Long-Term Care, Consumer Federation of America, and 60 other organizations submitted one request; Public Citizen Health Research Group submitted the other request. Collectively, the petitioners stated that many of the deaths and injuries involving APBRs result from asphyxiation caused by entrapment within openings of the APBR rail or between the rail and the mattress or bed frame. The petitioners requested that the CPSC initiate rulemaking proceedings under section 8 of the CPSA to ban all APBRs. Alternatively, petitioners requested that the Commission initiate a rulemaking under section 9 of the CPSA to promulgate mandatory standards, including warning labels, to reduce the unreasonable risk of asphyxiation and entrapment posed by APBRs. Petitioners also requested action under section 27(e) of the CPSA to require manufacturers of APBRs to provide performance and technical data regarding the safety of their products.

The CPSC docketed the petition requests as a single petition: Petition CP 13-1, Petition Requesting a Ban or Standard on APBRs under the CPSA. On June 4, 2013, the Commission published a notice in the *Federal Register* seeking public comment on the petition. 78 FR 33393. Also in 2013, ASTM International (ASTM) formed the ASTM F15.70 subcommittee to begin developing a voluntary standard for APBRs.

On April 23, 2014, staff sent a briefing package on APBRs to the Commission (Staff's 2014 briefing package).[1] In that briefing package, staff recommended the Commission defer a

[1] Available at: https://www.cpsc.gov/s3fs-public/pdfs/foia_PetitionCP131RequestforBanorStandardforAdultPortableBedRail.pdf

decision on the petition until a voluntary standard for APBRs was developed and evaluated by staff. On April 29, 2014, the Commission voted to defer the petition pending ASTM's further work on a voluntary standard.

On April 28, 2015, the Commission voted again to defer a decision on the petition to allow the ASTM voluntary standard development process additional time to continue. Throughout this period, staff participated in the ASTM F15.70 subcommittee to develop the voluntary standard for APBRs. In August 2017, ASTM published the voluntary standard, ASTM F3186-17, *Standard Specification for Adult Portable Bed Rails and Related Products*.

On July 15, 2020, staff provided the Commission its review of ASTM F3186-17 (Staff's 2020 briefing package).[2] Staff indicated that ASTM F3186-17 would adequately address the hazards identified in the known incident reports if there were certain modifications to the labeling, warning statements, and instructional literature requirements and to physical test requirements. However, when staff assessed compliance to the voluntary standard, staff found no market compliance with the voluntary standard.

In June 2020, CPSC's Office of Compliance sent a letter to 19 known APBR manufacturers, urging industry members to stop manufacturing, distributing, and selling APBRs that do not comply with ASTM F3186-17. Staff also continued to engage actively at the ASTM F15.70 subcommittee meetings. Staff presented and explained its testing results to the subcommittee members, provided the subcommittee with Compliance's letter to industry, supplied updated incident data for the subcommittee's review, and participated as technical experts on all subcommittee task groups.

[2] Available at: https://www.cpsc.gov/s3fs-public/Update%20on%20Peititon%20CP%2013-1%20-%20Requesting%20a%20Ban%20or%20Mandatory%20Standard%20on%20Adult%20Portable%20Bed%20Rails.pdf?kiDixW5Z7x9xcOqjxSeS3QpvspdfQMBY

On March 9, 2022, staff sent to the Commission another briefing package regarding ASTM F3186-17 (Staff's 2022 briefing package).[3] That briefing package updated the Staff's 2020 briefing package with incident data that included all known APBR safety incidents from January 2003 through September 2021. In addition, Staff's 2022 briefing package discussed the results of the two rounds of testing staff had conducted on APBRs, and the continuing lack of compliance with ASTM's voluntary standard. Staff recommended that the Commission grant the petition and direct staff to prepare a notice of proposed rulemaking (NPR) to address the entrapment hazards associated with APBRs. On March 16, 2022, the Commission voted to grant Petition CP 13-1 and directed staff to proceed with a draft NPR.

On September 21, 2022, staff sent the Commission an NPR briefing package for APBRs.[4] On October 13, 2022, the Commission voted to publish the NPR for APBRs in the *Federal Register*. On November 9, 2022, the Commission published its NPR in the *Federal Register*, determining preliminarily that there is an unreasonable risk of injury and death associated with entrapment hazards from APBRs. To address those risks, the Commission proposed a rule under the CPSA that would require APBRs to meet the requirements of the ASTM F3186-17 voluntary standard, with modifications. 87 FR 67586. The Commission received seven written comments regarding the NPR. Although the Commission offered an opportunity for interested parties to present oral comments on the NPR, the Commission did not receive any requests to provide oral comments.

[3] Available at: https://www.cpsc.gov/s3fs-public/Petition-Requesting-a-Ban-or-Standard-on-Adult-Portable-Bed-Rails-Petition-CP-13-1.pdf
[4] Available at: https://www.cpsc.gov/s3fs-public/ProposedRuleSafetyStandardforAdultPortableBedRails.pdf?VersionId=Ypa89Iczh13C40Tq7EJRSMDZoatChf1.

In this final rule, the Commission determines that APBRs pose an unreasonable risk of injuries and deaths associated with entrapment hazards.[5] To address this risk, the Commission adopts ASTM F3186-17, with modifications, to improve the safety of APBRs. The information discussed in this preamble is derived primarily from CPSC staff's briefing package for the NPR and briefing package for the final rule (staff's final rule briefing package).[6]

This final rule is authorized by the CPSA, 15 U.S.C. 2051-2084. Section 7(a) of the CPSA authorizes the Commission to promulgate a mandatory consumer product safety standard that sets forth performance or labeling requirements for a consumer product if such requirements are reasonably necessary to prevent or reduce an unreasonable risk of injury. 15 U.S.C. 2056(a). Section 9 of the CPSA specifies the procedure that the Commission must follow to issue a consumer product safety standard under section 7 of the CPSA. In accordance with section 9, the Commission is issuing this final rule for APBRs.

According to section 9(f)(1) of the CPSA, before promulgating a consumer product safety rule the Commission must consider, and make appropriate findings to be included in the rule, on the following issues:

- The degree and nature of the risk of injury that the rule is designed to eliminate or reduce;
- The approximate number of consumer products subject to the rule;
- The need of the public for the products subject to the rule and the probable effect the rule will have on utility, cost, or availability of such products; and
- Any means to achieve the objective of the rule while minimizing adverse effects on competition, manufacturing, and commercial practices.

[5] The Commission voted X-X to approve this notice.
[6] Available at: [INSERT HYPERLINK].

15 U.S.C. 2058(f)(1).

Under section 9(f)(3) of the CPSA, to issue a final rule, the Commission must find that the rule is "reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with such product" and that issuing the rule is in the public interest. *Id.* 2058(f)(3)(A) and (B). Additionally, if a voluntary standard addressing the risk of injury has been adopted and implemented, the Commission must find that:

- The voluntary standard is not likely to eliminate or adequately reduce the risk of injury, or
- Substantial compliance with the voluntary standard is unlikely.

Id. 2058(f)(3)(D). The Commission also must find that expected benefits of the rule bear a reasonable relationship to its costs and that the rule imposes the least burdensome requirements that would adequately reduce the risk of injury. *Id.* 2058(f)(3)(E) and (F).

II. The Subject Products

Several types of bed rails under CPSC jurisdiction are available to consumers.[7] ASTM F3186-17 (Section 1.2) describes "portable bed rails and related products" as products installed by consumers and "not designed as part of the bed by the bed manufacturer." Generally, APBRs within CPSC's jurisdiction include products that are installed or used alongside a bed by consumers and are intended to reduce the risk of falling from the bed, assist the consumer in

[7] Information on adult bed rails regulated by the U.S. Food and Drug Administration (FDA) is available at: www.fda.gov/medical-devices/bed-rail-safety/safety-concerns-about-bed-rails. FDA regulations do not reference "bed rails" or "bed handles;" rather, they refer to "movable and latchable side rails." *See* 21 CFR 880.5100, 880.5110, 880.5120. Bed rails that are an accessory or appurtenance to regulated hospital beds are considered by the FDA to have a medical purpose and to be devices subject to FDA jurisdiction. APBRs intended for use with a non-FDA regulated bed and that are not otherwise a medical device fall under the CPSC's jurisdiction regardless of the bed's location (e.g., long-term care facility, hospice, or residence). ASTM F3186-17 (Section 1.3) covers both APBRs that meet the definition of a medical device and APBRs that are not medical devices.

repositioning in the bed, or assist the consumer in transitioning into or out of the bed. Figure 1 below shows four common types of APBRs.

Figure 1: General examples of APBR types – (1) Full-Length Bed Rail, (2) Bed Cane, (3) Bed Handle, and (4) Half-Length Bed Rail

Because of the similarity in design and means of attachment to the side of the bed, products intended for both types of uses can present the same potential entrapment hazards, as discussed in Section III of this preamble.

In September and October 2021, CPSC staff conducted an online search that identified 12 firms supplying 65 distinct APBR models. Retail prices for the identified APBR models ranged from $38 to $275. Based on an interview with one APBR manufacturer's representative and market information from the identified APBR models, CPSC staff estimates that in 2021, the mean retail price was $50 per APBR; total market revenues were approximately $9 million; and the number of APBRs sold that year was approximately 180,000 units. *See* Tab C of the staff's briefing package for the final rule for additional details.

III. Risk of Injury

In the NPR proceeding, CPSC staff summarized the data on deaths and injuries involving APBRs. *See* Tab A: Division of Hazard Analysis: Directorate for Epidemiology (EPHA) of the staff NPR briefing package. In particular, staff reviewed Consumer Product Safety Risk Management System (CPSRMS) injury cases and National Electronic Injury Surveillance System **(**NEISS) injury cases that occurred in the period from January 1, 2003, through December 31, 2021. The Commission received no comments on that analysis. The final regulatory analysis is substantively the same as the preliminary analysis.

A. CPSRMS Reports

Staff identified a total of 332 incident reports for the period January 2003 to December 2021. Of these, 310 were reports of fatalities, and 22 were reports of nonfatal incidents. Most of the incidents were identified from death certificates, medical examiner reports, or coroner reports. Death certificate data often have lag time of approximately two to three years from the initial date of reporting. As the APBR data in CPSRMS are heavily reliant on death certificates, data collection is ongoing and incident data for 2020 and 2021 should be considered incomplete and likely to increase.

The remaining incidents were extracted from various sources including newspaper clippings, consumer reports, and manufacturer and retailer reports to CPSC. These documents contain limited information on incident scenarios. The age range of victims in the 305 fatal incidents for which age was reported was 14 to 103 years. More than 75 percent of the incident victims were age 70 or older, and almost 80 percent of the reported fatalities involved victims 70 or older. Table 1 below presents the distribution of these APBR incidents by age.

Table 1: Distribution of Reported APBR-Related Incidents by Age

Age Group (Years)	Fatalities	Nonfatalities	Total
13–29	7	0	7
30–59	30	0	30
60–69	22	0	22
70–79	47	2	49
80–89	124	2	126
90 or older	75	1	76
Unknown/Unspecified	5	17	22
Total	**310**	**22**	**332**

Source: CPSRMS (2003-2021).

Table 2 details the distribution of these APBR-related incidents by gender. Approximately 70 percent of all incident victims and incident fatalities were female.

Table 2: Distribution of Reported APBR-Related Incidents by Gender

Gender	Fatalities	Nonfatalities	Total
Male	88	7	95
Female	221	8	229
Unknown/Unspecified	1	7	8
Total	**310**	**22**	**332**

Source: CPSRMS (2003-2021).

Approximately 50 percent of all APBR-related incidents and fatalities occurred at home. Other commonly reported locations included nursing homes, assisted living facilities, and residential institutions.[8] Table 3 below shows the frequency of each location reported.

Table 3: Distribution of Reported APBR-Related Incidents by Location

Location	Fatalities	Nonfatalities	Total
Home	158	6	164
Nursing Home	50	0	50
Assisted Living Facility	40	2	42
Residential Institution	14	0	14
*Other**	23	0	23
Unknown/Not Reported	25	14	39
Total	**310**	**22**	**332**

Source: CPSRMS (2003-2021).

*Includes care home/center, foster home, group home, retirement center, adult family home and hospice.

[8] All of these reported incidents occurred with APBRs that were identified as being within the CPSC's jurisdiction.

The majority of reports, 58 percent, indicated that the victim suffered from at least one underlying medical condition. Almost 34 percent were reported to have more than one medical condition. Table 4 below summarizes the most common underlying medical conditions reported.

Table 4: Distribution of Reported APBR-Related Incidents by Medical Condition

Condition	Fatalities	Nonfatalities	Total
Cardiovascular disease	87	0	87
Alzheimer's/Dementia/Mental	73	0	73
Mobility/Paralysis/Stroke	20	0	20
Parkinson's disease	17	1	18
Pulmonary disease	11	0	11
Cancer	7	0	7
Cerebral palsy	6	0	6
Multiple sclerosis	5	0	5
*Other**	21	0	21
Unknown/Not Reported	123	21	144

Source: Staff briefing memorandum in the staff package for the final rule.

B. NEISS Reports

Between January 2003 and December 2021, there were an estimated 79,500 injuries related to adult bed rails treated in hospital emergency departments (EDs) across the United States. There was a statistically significant increasing trend in injuries during this period. In the vast majority of NEISS cases, there was insufficient information available in the case narrative for CPSC staff to determine whether the bed rail product involved was specifically an adult portable bed rail, or another type of bed rail; only one case narrative specifies the product involved as an adult portable bed rail. Hence, the estimates presented in Table 5, which provides an overview of the estimated number of adult bed rail-related injuries per year, may be an overestimate. An estimated injury rate per 100,000 population has also been calculated, based on estimates of population ages 13 and older provided by the U.S. Census Bureau.

Table 5: NEISS Estimates for Injuries Related to Adult Bed Rails, January 2003–December 2021

Year	Estimate	Sample Size	Injury Rate[9]
2003	4,500	98	1.88
2004	3,400	82	1.39
2005	3,900	94	1.61
2006	3,400	72	1.38
2007	4,300	98	1.73
2008	4,200	102	1.67
2009	3,600	98	1.42
2010	4,000	100	1.56
2011	3,700	95	1.44
2012	3,100	81	1.20
2013	4,700	127	1.79
2014	4,400	108	1.66
2015	4,600	112	1.73
2016	3,700	91	1.36
2017	4,900	128	1.81
2018	4,300	104	1.55
2019	4,500	112	1.63
2020	5,100	113	1.82
2021	5,100	131	1.83
Total	79,500	1,946	

Source: Staff briefing memorandum in staff package for the final rule.

The vast majority (88 percent) of the ED patients were treated and released or examined and released without treatment, while approximately 11 percent were hospitalized or held for observation. There was only one NEISS case that involved a death; the remaining 1,945 involving nonfatal injuries. The one NEISS case involving a death is separate from any of the CPSRMS incidents, and it was unclear what specific type of product was involved.

C. Hazard Patterns

As explained in Tabs B and C of staff's NPR briefing package, the vast majority of incident victims in CPSRMS were members of vulnerable populations.

- More than 75 percent of the victims were age 70 or older.

[9] Obtained by dividing NEISS estimates by U.S. Census Bureau population estimate for the respective year (for ages 13+). Latest data can be found at: National Population by Characteristics: 2020-2021 (census.gov), https://www.census.gov/data/tables/time-series/demo/popest/2020s-national-detail.html.

- More than 80 percent of the reported fatalities involved victims ages 70 or older.
- Fifty-eight percent of victims suffered from at least one underlying medical condition.
- Almost 34 percent of victims were reported to have more than one medical condition.

Staff grouped the hazard types into four categories based on the bed rail's role in the incident. The categories are listed in order of highest to lowest frequency.

- **Rail Entrapment:** There were 284 fatalities and two not-fatal injuries related to rail entrapment. This category includes incidents in which the victim was caught, stuck, wedged, or trapped between the mattress/bed and the bed rail, between bed rail bars, between a commode and rail, between the floor and rail, between the night table and rail, or between a dresser and rail. Based on the narratives, the most frequently injured body parts were the neck and head.
- **Falls:** There were 23 deaths, one nonfatal knee fracture, and one non-injury incident related to falls. This category includes incidents in which the victim fell off the bed, fell and hit the bed rail, or hit and fell near the bed rail, and fell after climbing over the bed rail.
- **Structural Integrity:** There were 11 incidents related to structural component problems (weld of bed rail broke and bed rail not sturdy). This category includes one laceration, one head bump, one bruise, two unspecified injuries, and six non-injury incidents.
- **Miscellaneous:** There were 10 incidents with miscellaneous problems (hanging on the bed rail after garment got caught, hand, arm, or leg laceration, pinched radial nerve against the bed rail, complaint about a misleading label, complaint about a bed rail that was noncompliant with the ASTM standard, and a claim against a bed rail

manufacturer about an unspecified issue). This category includes three deaths, three lacerations, one pinched nerve, one unspecified injury, and two non-injury incidents.

Rail entrapment, the most common hazard pattern among all reported incidents, accounted for more than 90 percent (284 of 310) of the fatal incidents. A review of the In-Depth Investigations (IDIs)[10] showed that the victims were typically found with their torso between the product and the mattress frame, with their neck resting on the lower bar. Three other hazard patterns were also reported: (1) chin resting on the bar; (2) slumped backwards, partially suspended with the thorax lodged and compressed in the gap between the rail and mattress; and (3) slumped through the bar opening. The medical examiners in these cases listed the cause of death as "positional asphyxia," with an additional list of "underlying factors" or "contributory causes." Staff's analysis of the data revealed that the head and neck were the body parts most frequently entrapped, with positional asphyxia (neck against rail) identified as the most common cause of death. Neck compression, with or without airway blockage, can result in death, even when the body remains partially supported, because blood vessels taking blood to and from the brain and the carotid sinuses are located in soft tissues of the neck and are relatively unprotected.

The vast majority of nonfatal incident reports (all reports except one) did not list any underlying medical condition. Of the 310 fatal incidents, approximately 34 percent reported the victim to have multiple medical conditions, and approximately 58 percent of incidents reported at least one underlying medical condition. Preexisting chronic medical conditions or disorders included Alzheimer's disease, dementia, and other mental limitations; Parkinson's disease; cerebral palsy; multiple sclerosis; Lesch-Nyhan syndrome; amyotrophic lateral sclerosis; cancer; cardiovascular disease; and pulmonary disease. Other conditions included victims with stroke,

[10] IDIs contain summaries of reports of investigations into events surrounding product-related injuries or incidents based on victim/witness interviews.

paralysis, seizures, heavy sedation, and drug ingestion. These factors can limit mobility or mental acuity and contribute to the risk of death by entrapment, because individuals with these conditions are particularly vulnerable and often cannot respond to the danger and free themselves. As discussed in Tab B of the staff's NPR briefing package, adult aging issues can contribute to entrapments, including age-related declines in muscular strength, muscular power, motor control and coordination, and balance. Consumers 70 years and older, who are the victims in most APBR-related fatalities, are especially vulnerable to such age-related declines.

CPSC staff identified falls as the second most common hazard pattern associated with APBRs, accounting for 25 incidents (8 percent), 23 of which resulted in a fatality. Staff found that most falls associated with APBRs involve the victim falling against or striking the APBR. A minority of fall-related incidents, according to staff's review, involved the victim deliberately climbing over the APBR.

IV. ASTM F3186-17

To issue a final rule under section 9(f)(3) of the CPSA if a voluntary standard addressing the risk of injury has been adopted and implemented, the Commission must find that:

- The voluntary standard is not likely to eliminate or adequately reduce the risk of injury, or
- Substantial compliance with the voluntary standard is unlikely.

Staff's review of ASTM F3186-17 shows that the voluntary standard, with modifications, is likely to eliminate or adequately reduce the entrapment hazards associated with ABPRs. The Commission determines, however, that the voluntary standard is not likely to eliminate or adequately reduce the risk of entrapments on ABPRs without modifications. In addition, based on testing of ABPRs conducted by CPSC staff as discussed below, the Commission determines

that substantial compliance with the voluntary standard is unlikely. Accordingly, in the final rule the Commission incorporates by reference ASTM F3186-17, with modifications, to address the entrapment hazards associated with APBRs.

A. Assessment of ASTM F3186-17 Performance Requirements

1. Terminology

ASTM F3186-17 establishes performance requirements for APBRs, including requirements for resistance to entrapment, marking and labeling, and instructional literature. Section 3.1.1 of ASTM F3186-17 defines "adult portable bed rail" as:

> [A]n adjacent type bed rail, grab bar, assistive bar, transfer aid, cane, or rail (henceforth identified as the product or products) intended by the manufacturer to be installed on, against, or adjacent to an adult bed. The product may vary in lengths (for example, full, half, or partial rails, grab bar or handle or transfer post or pole) and is intended by the manufacturer to aid the bed occupant in moving on the bed surface, in entering or exiting the bed, to minimize the possibility of falling out of bed, or for other similar purposes. This includes similar products that are likely to be used for these purposes even if this is not explicitly stated by the manufacturer. However, the standard does not address all products that might be so used, for example, a chair.

ASTM F3186-17 (Section 3.1.2) defines "adjacent type bed rail" as:

> [A] portable bed rail or related product in which the guard portion (portion that an adult would contact when rolling toward the mattress edge) is essentially a vertical plane or pole that is positioned against the side of the mattress.

The Commission determines that these definitions are appropriate for addressing hazards associated with APBRs that: (1) are installed or used along the side of a bed and intended to

reduce the risk of falling from the bed; (2) assist the consumer in repositioning in the bed; or 3) assist the consumer in transitioning into or out of the bed.

2. General Requirements

Section 5 of ASTM F3186-17 sets out general requirements. Section 5.1 requires that there will be no hazardous sharp points or edges. Section 5.2 states that any exposed parts shall be smooth and free from rough edges. Section 5.3 requires that products covered by the standard that are installed on an adjustable bed that articulates must meet the performance requirements when the bed is in either the flat or articulated position. General requirements mandating smooth edges on exposed parts improve safety by preventing potential lacerations or skin injuries from APBRs. In addition, testing APBR products on articulating beds allows assessment of openings that could potentially lead to entrapment after the bed is adjusted from the flat position to the articulated position.

3. Performance Requirements

In addition to the general requirements, several performance requirements in ASTM F3186-17 are intended to address the risk of injury associated with APBRs. These include requirements for assembly, structural integrity, retention system performance, and fall and entrapment prevention.

a. Misassembly and Misinstallation

Effectively addressing the entrapment hazard associated with APBRs depends upon, among other things, consumers assembling and installing the product properly. ASTM F3186-17 includes performance requirements intended to improve the likelihood that the APBR will be assembled and installed properly. For example:

- Section 6.1 sets forth a requirement for products to include a retention system, which maintains the installed product in position without requiring readjustment of the components. This retention system must be permanently attached to the APBR once it has been assembled and must not be removable without the use of a tool.
- Section 6.2 includes structural integrity requirements that require the product to withstand testing without deforming or changing dimensions.
- Section 6.5 requires that structural components and retention system components must not be capable of being misassembled, which the standard defines as the APBR being assembled in a way that appears functional but would not meet the retention system (Section 6.1), structural integrity (6.2), entrapment (6.3), or openings (6.4) requirements.

The requirement that retention systems be permanently attached to the APBR once it has been assembled, and removable only with a tool, reduces the likelihood that consumers will misplace the retention system and increases the likelihood that consumers, including secondary users, will continue to use the retention system. The requirement that structural and retention system components not be misassembled reduces the risk of injury or death that could arise from the consumer omitting key parts of the APBR (e.g., a center rail) during assembly, in ways that could result in entrapment or other hazards.

b. Falls

Falls were the second most common hazard pattern in the incident data, accounting for 25 incidents (8 percent). If the fall was triggered by the APBR becoming dislodged, or if its position shifted, then these incidents potentially may be addressed by the voluntary standard's structural integrity testing and the requirement of a permanently attached retention system to maintain the installed product in position. However, some fall-related incidents involved the

victim deliberately climbing over the APBR and this requirement may not prevent such consumers from falling over the bed rail.

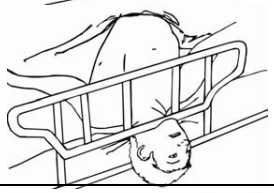
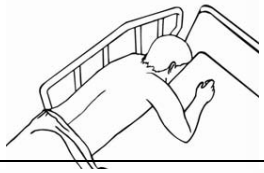
c. Entrapment Testing

Staff identified entrapment as the most prevalent hazard pattern among the incidents. Section 6.3 of ASTM F3186-17 requires products to be tested to assess the potential for entrapment in four different zones. These zones represent four of the seven sectors identified by the FDA in its 2006 guidance document, Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment (FDA, 2006), as potential areas of entrapment in hospital bed systems.[11] APBRs present a similar entrapment hazard in these four zones. ASTM F3186-17 specifies the FDA probe to test entrapment zones.

Section 8.4 defines the four entrapment zones tested under ASTM F3186-17, which are: (1) within the product; (2) between rail support(s) and the bed mattress, when applicable, under the product; (3) between the product and the mattress; and (4) between the underside of the end of the product and the mattress. Entrapment testing to ASTM F3186-17 is performed using the anthropometric "entrapment test probe," which is the cone and cylinder tool described in the 2006 FDA guidance document (Section 7.2). In addition, some entrapment testing requires using a force gauge to test the force applied on the test probe (Section 7.3). Table 6 below, describes the four entrapment zones, with illustrations from the 2006 FDA guidance document of sample entrapments within each of these zones.

[11] The FDA guidance document is available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment. (FDA, 2016). Three of the zones identified in the FDA guidance (Zone 5, Zone 6, and Zone 7) are not applicable to APBRs, or could not be tested for entrapment, and therefore, they are excluded from ASTM F3186-17.

Table 5: ASTM F3186 – 17 Entrapment Zones

Zone 1: Within the Product Entrapment in any open space within the perimeter of the APBR	
Zone 2: Between Rail Support(s) and the Bed Mattress, When Applicable, Under the Product Entrapment under the bottom edge of the APBR, between the rail supports or next to a single rail support, against the mattress	
Zone 3: Between the Product and the Mattress Entrapment in the space between the inside surface of the APBR and the side of the mattress	
Zone 4: Between the Underside of the End of the Product and the Mattress Entrapment under the lowermost portion of the end of the APBR, against the mattress	

Staff's review of the rail entrapment incidents, test requirements, and test methods showed that most of the reported entrapment fatalities involved one of the four zones listed above. Specifically, staff could determine the entrapment location of 214 of the 284 fatal incidents, and all but six of these cases occurred in one of the four zones of entrapment tested in ASTM F3186-17, as shown in Table 7 below. Based on this analysis, it is likely that most of the 70 incidents for which there was insufficient information to identify the location of the entrapment also involved one of these four zones. *See* staff's briefing packages for the NPR and the final rule.

Table 6: Rail entrapment incident locations relative to ASTM F3186-17 entrapment zones

Rail Entrapment Location	Entrapment Testing Location	No. of Fatalities
Between APBR and mattress	Zones 2, 3, or 4	200
Within APBR itself	Zone 1	8
Against outside of APBR	None	5
Between APBR and headboard	None (Zone 6)	1
Unknown location	Unknown	70
Total		284

Staff's evaluation found that APBR entrapments predominantly occur in Zones 1 through 4, and this is consistent with the FDA's finding that these four zones accounted for about 80 percent of hospital bed rail entrapment events reported to the FDA. FDA's recommended dimensional limits for these zones and the anthropometric test probe serve as the basis for the entrapment requirements of ASTM F3186-17. CPSC's review indicates that the performance requirements in the standard, which are based on identified entrapment patterns and related anthropometric data, would effectively address the entrapment hazard patterns related to APBRs with modifications, discussed below, to eliminate or adequately reduce the unreasonable risk of injury of entrapments.

d. Labeling, Warning, and Instructional Literature Requirements

Section 9.1 of ASTM F3186-17 specifies that the labeling on the APBR and its retail packaging must be marked with the type and size of beds and mattresses, including the mattress thickness range for which the APBR is intended. In addition, the labeling and retail packaging on the APBR must state the appropriate distance between an installed APBR and the headboard or footboard of the bed. ASTM F3186-17 requires labeling on the product and its retail packaging to indicate how to correctly install the ABPR at the specified distance from the headboard or footboard to prevent entrapment. This hazard is addressed by requiring labeling on the APBR to state the appropriate distance between an installed APBR and the headboard or footboard of the bed. Section 9.1 also specifies that all on-product labels must be permanent.

Section 9.2 establishes requirements for warning statements that must appear on the APBR and its retail packaging, instructions, and digital or print advertising. The warning statements must be easy to understand, and any other labels or written instructions provided

along with the required statements cannot contradict or confuse the meaning of the required warnings or otherwise be misleading.

Section 11 specifies requirements for instructional literature that must accompany APBRs. The instructions provided must be easy to read and understand; include assembly, installation, maintenance, cleaning, operation, and adjustment instructions and warnings, where applicable; include drawings or diagrams to provide a better understanding of set up and operation of the product; include drawings that depict all the entrapment zones; and include all warning statements specified in Section 9.2, including warnings about product damage or misalignment.

Although requirements for labeling, warning, and instructional requirements are less effective at reducing hazards than product designs that directly address known hazards, these requirements in the standard improve safety by addressing risks that may not be eliminated through design.

Although many provisions of ASTM F3186-17 do improve safety, for the reasons discussed in section V. of the preamble of the NPR, the Commission determines that, without additional modifications, the voluntary standard is insufficient to eliminate or adequately reduce the unreasonable risk of injury of entrapments from APBRs.

B. Assessment of Compliance to ASTM F3186-17

Staff conducted two rounds of market compliance testing to ASTM F3186-17: the first round in 2018 and 2019, the second round in 2021. In both rounds, no APBRs met all requirements of ASTM F3186-17. All products failed at least one critical mechanical requirement, such as retention strap performance, structural integrity, and entrapment. As described in Tabs C and D of the staff's NPR briefing package and the staff's final rule briefing

package, an APBR that fails any one mechanical performance requirement could result in a fatal entrapment. Furthermore, all products failed the labeling, warning, and instructional requirements. This section discusses market compliance with ASTM F3186-17.

1. 2018-2019 Market Compliance Testing

From 2018 through 2019, staff of CPSC's Directorate for Laboratory Sciences, Division of Mechanical Engineering, tested 35 randomly selected APBR models for compliance with ASTM F3186-17. That voluntary standard became effective in August 2017. APBRs were purchased in 2018. Staff found that none of the 35 sampled products conformed to the voluntary standard. As shown in Table 8 below, compliance varied depending on the relevant section of the voluntary standard. Overall, 33 APBR models did not meet the entrapment performance requirements, and none of the 35 models met the labeling, warnings, or instructional literature requirements.

Table 7: ASTM F3186-17, 2018 APBR Market Compliance Testing Result Summary

Section		Title	# of Failed Samples (Of 35 Total Samples Tested)	Failure Rate
General Requirements	5.1	Hazardous Points/Edges	0	0%
	5.2	Jagged Surfaces	0	0%
	5.3	Articulated Beds	0	0%
Performance Requirements	6.1	Retention Systems	28	80%
	6.2	Structural Integrity	15	43%
	6.3	Entrapment	33	94%
	6.4	Openings	0	0%
	6.5	Misassembled Products	8	23%
Labels and Warnings Requirements	9.1	Labeling	35	100%
	9.2	Warning Statements	35	100%
Instructional Literature	11	Instructional Literature	35	100%

Of the 35 APBR models staff tested, 33 failed at least one of the entrapment requirements for the four different zones in and around the APBR. In other words, 94 percent of samples had at least one major zone where a body part could be entrapped. Furthermore, many samples failed the entrapment requirements in multiple zones: 14 failed the Zone 1 entrapment requirement; 27 failed Zone 2; 11 failed Zone 3; and 6 failed Zone 4.

Testing conducted by staff also revealed high failure rates for several other sections of the ASTM standard, including the retention system requirements (28 of 35 samples), and structural integrity requirements (15 of 35 samples). These types of failures indicate that the product may not stay rigidly in place after installation and will not adequately support the consumer during normal use conditions, such as leaning against the product. Not meeting these requirements thus significantly increases the likelihood of entrapment and fall hazards.

Retention system failures occurred when components were not permanently attached to the product, the retention strap permanently deflected or detached during the free end pull test,[12] or the retention system did not restrain the product during entrapment testing. Structural integrity failures occurred when the APBR did not extend at least 4 inches over the top of the thickest recommended mattress, or when fasteners loosened or detached during testing, causing the product to change dimensions.

All 35 models failed the labeling, warning, and instructional literature requirements. None of the 35 models fully met the following requirements: Section 9.1 for retail packaging and product labels; Section 9.2, which specifies that warning statements must appear on the product, its retail package, and its instructions; and Section 11's requirement to include instructional literature with required warning statements. None of the samples adequately instructed consumers how to safely install the APBR; nor did the samples adequately inform consumers of the known hazards related to APBRs. Detailed testing results are provided in Appendix A of the staff's NPR briefing package.

2. 2021 Market Compliance Testing

In 2021, staff conducted a second round of product testing to ASTM F3186-17 to determine if the additional time and outreach efforts by staff since 2018 were sufficient for manufacturers to increase their overall level of compliance to the standard. A representative total of 17 APBR products were procured for testing: these included all of the eight APBR models that staff identified as new to the market since the 2018 analysis, and nine additional, randomly selected models from the remaining models available in the market. The nine randomly selected models were products previously identified in the 2018 analysis as available

[12]The ASTM standard does not define "free-end." The final rule defines "free-end" as the location on the retention system that is designed to produce a counter force; it may be a single distinct point or a location on a loop.

for purchase at that time and were again included in 2021 to account for any changes to those models that may have improved their compliance to the voluntary standard.

The 2021 testing, like the 2018 analysis, was designed to assess overall compliance to the voluntary standard, with a focus on certain sections of ASTM F3186-17 including Retention Systems, Structural Integrity, Entrapment, Openings, Misassembled Products, Warning Statements, and Instructional Literature. All 17 samples failed at least one of these performance requirements. Detailed testing results are provided in Appendix B of the staff's NPR briefing package. Because performance testing of a sample was stopped after failing to meet at least one performance requirement, the data collected may not account for all the potential nonconformities for each product.

Additionally, none of the 17 models met the labeling, warnings, and instructional literature requirements. As shown in Table 9 below, the failure modes of this analysis are similar to those in the 2018 analysis, indicating little-to-no significant change in the market over this time.

Table 8: ASTM F3186-17, 2021 APBR Market Compliance Testing Result Summary

Section		Title	# of Failed Samples	# of Samples Tested
General Requirements	5.1	Hazardous Points/Edges	0	17
	5.2	Jagged Surfaces	0	17
	5.3	Articulated Beds	-	0
Performance Requirements	6.1	Retention Systems	13	17
	6.2	Structural Integrity	7	7
	6.3	Entrapment	14	16
	6.4	Openings	-	0
	6.5	Misassembled Products	1	1
Labels and Warnings Requirements	9.1	Labeling	17	17
	9.2	Warning Statements	17	17
Instructional Literature	11	Instructional Literature	17	17

3. CPSA Section 15 Compliance Actions 2021–2022

CPSC has issued five public warnings regarding specific APBRs that did not comply with ASTM F3186-17. In April 2021, CPSC warned consumers to stop using three models of APBRs manufactured by Bed Handles, Inc., because the products pose an entrapment hazard.[13] Bed Handles, Inc., manufactured approximately 193,000 units of the bed rails, and CPSC is aware of four entrapment deaths associated with the product.

In December 2021, CPSC announced voluntary recalls of APBRs manufactured by three firms, due to the entrapment hazard and risk of death by asphyxia posed by their products:

- Drive DeVilbiss Healthcare (496,100 units, 2 deaths);[14]
- Compass Health Brands (104,900 units, 3 deaths); and[15]
- Essential Medical Supply, Inc. (272,000 units, 1 death).[16]

In June 2022, CPSC warned consumers to stop using 10 models of APBRs manufactured and sold by Mobility Transfer Systems, Inc. from 1992 to 2021, and by Metal Tubing USA, Inc. in 2021 and 2022. Three entrapment deaths involving one of these models have occurred.[17] Neither of the two manufacturers agreed to conduct a recall. Approximately 285,000 units were manufactured.

[13] Press Release (PR) #21-122, https://www.cpsc.gov/Newsroom/News-Releases/2021/CPSC-Warns-Consumers-to-Stop-Use-of-Three-Models-of-Adult-Portable-Bed-Rails-Manufactured-by-Bed-Handles-Inc-Due-to-Entrapment-Asphyxia-Hazard.

[14] PR #22-025, https://www.cpsc.gov/Recalls/2022/Drive-DeVilbiss-Healthcare-Recalls-Adult-Portable-Bed-Rails-After-Two-Deaths-Entrapment-and-Asphyxiation-Hazards.

[15] PR #22-040, https://www.cpsc.gov/Recalls/2022/Compass-Health-Brands-Recalls-Carex-Adult-Portable-Bed-Rails-After-Three-Deaths-Entrapment-and-Asphyxiation-Hazards.

[16] PR #22-039, https://www.cpsc.gov/Recalls/2022/Essential-Medical-Supply-Recalls-Adult-Portable-Bed-Rails-Due-to-Entrapment-and-Asphyxia-Hazard-One-Death-Reported.

[17] PR #22-148, https://www.cpsc.gov/Newsroom/News-Releases/2022/CPSC-Urges-Consumers-to-Immediately-Stop-Use-of-Mobility-Transfer-Systems-Adult-Portable-Bed-Rails-Due-to-Entrapment-and-Asphyxia-Hazard-Three-Deaths-Reported.

4. Market Compliance Testing Summary

The Commission determines that, without additional modifications as discussed in the NPR and below, the voluntary standard is insufficient to eliminate or adequately reduce the unreasonable risk of injury of entrapments presented by APBRs. Moreover, based on staff's test results showing that there is no market compliance with the voluntary standard, the Commission determines that substantial compliance to a voluntary adult portable bed rail safety standard is unlikely. Accordingly, the Commission rule incorporates by reference, ASTM F3186-17 with modifications, to require ABPR manufacturers to comply with the fundamental requirements of the mandatory standard and thereby improve safety.

V. Response to Comments

CPSC received seven written comments during the NPR comment period. The comments are available on: www.regulations.gov, by searching under docket number CPSC-2013-0022. For more details about the comments CPSC received on the NPR, see the final rule staff briefing package. This section describes key issues raised in the comments and CPSC's responses to them.

A. Banning APBRs

Comments: Four commenters addressed the issue of banning APBRs. Public Citizen urged the CPSC to withdraw its proposed rule and instead promulgate a rule under section 8 of the CPSA, declaring all currently marketed adult bed rails to be banned hazardous products. National Center for Health Research (NCHR), National Consumer Voice for Quality Long-Term Care (Consumer Voice), and California Advocates for Nursing Home Reform (CANHR) commented that they do not support a ban at this time. However, they stated that they would

support a ban on APBRs if the final rule is adopted and proves to be ineffective in preventing deaths and injuries resulting from APBR entrapment.

Response: At this time there is not sufficient evidence to support a ban on APBRs under section 8 of the CPSA. Under section 8 of the CPSA, to issue a ban, the Commission must find:

- a consumer product is being, or will be, distributed in commerce and such consumer product presents an unreasonable risk of injury; and
- no feasible consumer product safety standard under this Act would adequately protect the public from the unreasonable risk of injury associated with such product.

15 U.S.C. 2057. The Commission finds the final rule, promulgated under section 9, will adequately address the unreasonable risk of fatal and non-fatal injuries related to APBR entrapment. However, after the final rule is effective, staff will monitor data they become available, assessing the efficacy of the final rule.

B. Comments on Alternatives to Using APBRs and on Qualitative or Quantitative Value of APBRs

Comment: Gloria Black, NCHR, Consumer Voice, Public Citizen, and CANHR identified several alternatives to using APBRs, such as: bed trapezes, adjustable beds, non-slip mattress pads, bed exit alarms, body pillows, and medical attendees.[18] Gloria Black specifically identified "no cost options" including lowering the bed or placing the mattress on the floor to prevent falls, placing cushioning on the floor to prevent serious injury, and placing a sturdy nightstand or table next to the bed to assist individuals in getting in and out of bed. Additionally, CANHR stated that APBRs are "used primarily as physical restraints for the convenience of

[18] A bed trapeze is a product that consumers can use to get in out of bed or change position while in bed. It typically consists of a horizontal bar suspended from a metal frame. Bed trapezes are typically larger than adjacent-type bed rails and are therefore less portable.

others, and almost always unnecessary and in nursing homes" and per "the Nursing Home Reform Law of 1987's prohibition of physical restraints for the convenience of staff, safe alternatives to prevent injury from falls have been practiced for decades in compliant facilities."

Two comments addressed the qualitative or quantitative value of APBRs. Sarina Martin expressed a general concern that a ban on APBRs will increase the risk of falls in long-term care facilities. Consumer Voice was unaware of any qualitative or quantitative evidence concerning the utility that APBRs have for consumers relative to products that might be used as substitutes in the event APBRs are banned. However, Consumer Voice noted some consumers have expressed fears that a ban could limit their ability to leave their beds, lead to a decline in mobility and functioning and therefore increase their dependency, and result in decreased quality of life due to greater isolation.

Response: A ban on APBRs could leave consumers without a product that provides them with mobility and independence. APBR products help consumers by aiding them in safely staying in a bed and providing them with a safe grip for getting in/out of a bed and repositioning while in bed. Such products are particularly useful for consumers who live in a personal residence, rather than in a hospital or care facility, as supervision or assistance may be less readily available in a home environment. However, considering the number of fatal and non-fatal injuries from APBRs, the Commission considers the requirements for APBRs in the final rule to be necessary to address the risks. Consumers may choose to use alternatives to APBRs, but while these alternatives have been available to consumers, many injuries and deaths continue to occur. These alternatives alone have not adequately reduced the unreasonable risk of injury and death presented by APBRs, and thus the final rule is needed to address the identified hazards.

C. The Effect of the Proposed Rule on Long Term Care Facilities

Comment: Sarina Marlin expressed a general concern regarding the effect of the proposed rule on long-term care facilities. Ms. Marlin asserted that data from staff's NPR package indicates that a disproportionate number of recorded fatalities associated with APBRs occur in home settings when compared to Long Term Care Facilities.

Response: The fatality location ratios quoted by Ms. Marlin are drawn from the preamble of the NPR, in which staff identified 158, 50, 40, and 14 fatalities associated with APBR entrapment in homes, nursing homes, assisted living facilities, and residential institutions, respectively. Without knowing the level of exposure in these different treatment settings, one cannot infer that there are fewer fatalities per APBR in professional settings than in the home, or that APBRs in professional settings do not pose significant risk to the public, without knowing the number of APBRs in use in each setting. CPSC staff did not, and does not, possess this information nor data from which estimates of the number of APBRs in use in each setting may be drawn. No such information was submitted by the commenter. However, given that APBRs are marketed primarily to individual consumers, staff assesses that APBRs are more likely to be found in homes than in professional settings.[19]

The Commission disagrees with the commenter's assertion that an undue impact will occur to long term care facilities. In the NPR's Preliminary Regulatory Analysis, CPSC staff considered the effect of the proposed rule on APBR price, the dead weight loss (the lost consumer and producer surplus resulting from price-induced decrease in APBR sales) associated with the price change, cost, and net benefits. Staff estimated the proposed rule would increase

[19] Professional care facilities may use a variety of products, including APBRs and hospital bed rails, depending on the needs of the patient.

manufacturer costs in the first year by approximately $5.40 per APBR, of which $4.00 is expected to be passed on to APBR consumers (including commercial enterprises) in the form of higher prices. A $4.00 increase in APBR price represents less than 0.01 percent of the annual cost of a private room in an assisted living facility, and approximately half that already tiny percentage for a private room in a nursing home, which staff does not consider an undue burden for these facilities.[20]

D. Hole Size Requirements

Comment: Louis A. Ferreira, of Stoel Rives, LLP, representing Stander, Inc. (Stander), a seller of APBRs, suggests that the NPR's proposal to regulate the sizes of holes or slots that extend entirely through a wall section on an APBR is not reasonably necessary to prevent or reduce an unreasonable risk of injury. Stander disagreed with the Commission's proposal to make the opening requirements consistent with standards for other products such as Children's Portable Bed Rails and instead suggests that the final rule should only correct consistency errors concerning dimensions in Section 6.4 of the voluntary standard. Stander claimed that "the size of the holes do[es] not increase the risk of a fall of entrapment" and that "[t]here is not even evidence in the record that would support a conclusion that finger entrapment in the holes of an adult bed rail have ever caused an injury."

Response: As reported in Tab A of the staff briefing package for the NPR, about 7,400 of the estimated 79,500 adult bed rail-related injuries treated in emergency departments from 2003

[20] Genworth Financial, Inc., estimates the national median annual cost for a private room in assisted care facilities and nursing homes in the United States in 2021 at $54,000 and $108,405. Median Cost of Nursing Home, Assisted Living, & Home Care | Genworth.

to 2021 were hand or finger injuries. Of these, about 3,400 were identified as injuries to fingers, most of which involved crushing or laceration.[21]

Section 6.4 of ASTM F3186-17 addresses the risk of finger entrapment and laceration in small holes or openings. Changes to this section are necessary to correct errors and inconsistent measurement references. Specifically, in stating the dimensions of the rods used to conduct testing, the standard inaccurately refers to 13 mm as the equivalent to 5/8 in. (whereas 5/8 in. is approximately 16 mm). Also, while the standard allows different dimensions for holes or slots that do not exceed ¼ in. in depth, it refers to a drawing depicting a hole up to ".375 (9.53 mm) deep," or 3/8 in., shown below in Figure 2.

[21] NEISS data can be searched by the public through the CPSC NEISS On-Line Query System - https://www.cpsc.gov/cgibin/neissquery/home.aspx

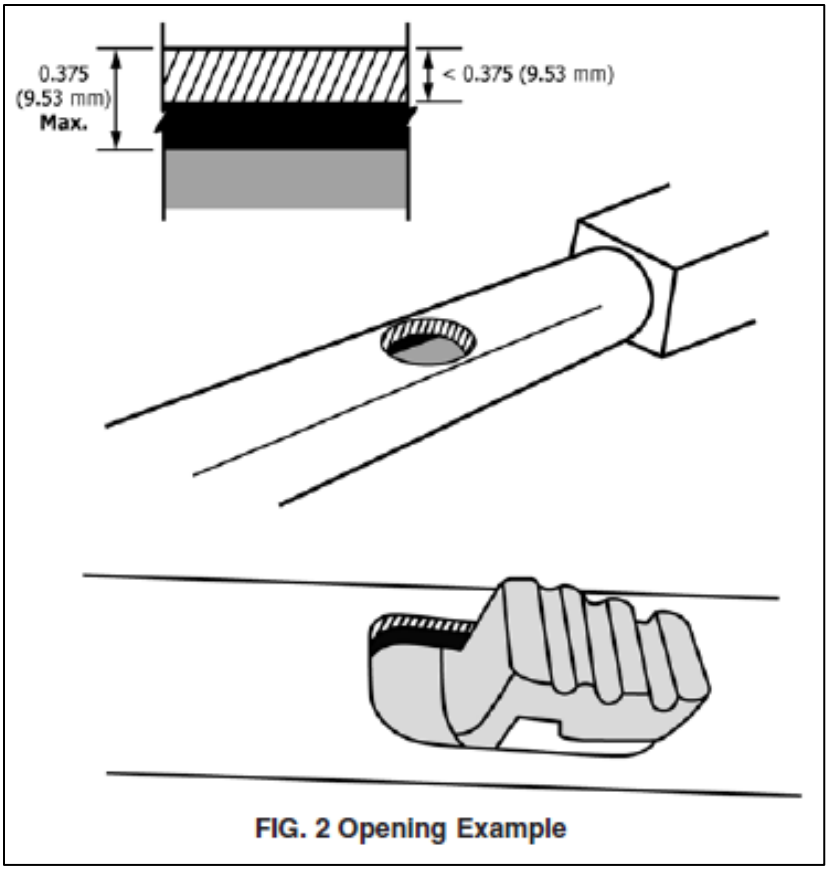


FIG. 2 Opening Example

Illustration from Figure 2 of ASTM F3186 – 17, Section 6.4

Further, the proposed changes in the NPR are necessary to adequately address the risk of injury because the hole dimensions referenced by the commenter are not effective in protecting vulnerable adult populations. Vulnerable adults are often smaller and more frail than other populations of adults and are more likely to use APBR products. The proposed changes in the NPR align the rule with other established children's product regulations that prevent hazards to a range of finger sizes that covers both children and adult users simultaneously.[22]

[22] It is also foreseeable that children may interact with APBRs, such as when visiting grandparents. The NPR's proposed modifications to the voluntary standard would protect children without creating any new hazards for adults.

The Commission therefore concludes the language proposed in the NPR is necessary to address the range of foreseeable consumer exposures to potentially hazardous holes in APBRs. Therefore, no change will be made to the final rule based on this comment.

E. Proposed Entrapment Test Modifications

Comment: Luis A. Ferreira, representing Stander, suggested that staff's proposed entrapment test modifications are ambiguous and inadequate. Stander expresses concern "that the ASTM Standard with the proposed modifications could be misinterpreted, and a product fail the test, not because of any unreasonable risk posed by the bed rail, but simply because a mattress is selected for testing that is so soft that the probe can be pulled beneath the bottom rail of the APBR." Stander suggests making changes to the proposed entrapment test requirements of the NPR.

Response: ASTM F3186-17 does not have a specific definition for "Entrapment Zone." Based on the commenter's interpretation of the entrapment test methods, the voluntary standard may not adequately describe what an Entrapment Zone is and why it is tested.

Each entrapment zone test addresses specific hazard patterns that are identified in both the FDA guidance document as well as staff's findings from the incident data. The hazard patterns associated with each entrapment zone are described below.

- Zone 1 testing addresses head-first entry into fully bounded openings within the structure of the rail.
- Zone 2 testing addresses head-first entry under the rail into any opening between the mattress compressed by the weight of a consumer's head and a section of the bedrail longer than 4.7 in.

- Zone 3 testing addresses entry of the head into a gap between the inside surface along the length of the rail and the mattress compressed by the weight of a consumer's head.
- Zone 4 addresses neck-first entrapment between the rail and mattress compressed by the weight of a consumer's head and neck at the ends of the rail.

We disagree with Stander's interpretations that entrapment zone hazards only exist where there are visible openings. According to the CPSC staff's analysis of the incident data, the area "between the rail and mattress" is the most common location for entrapment. The hazards related to each zone are present regardless of the locations of the supports but are dependent on the design of the rail in relation to the anthropometric dimensions of the user.

For example, per Zone 2, the known hazard is head-first entry under the rail in any section longer than the anthropometric head dimension of the entrapment test probe, which is 4.7 inches. Therefore, in Figure 1of the final rule below, both the left and right areas should meet Zone 2 requirements, in addition to the other applicable tests, to ensure the product adequately addresses the known hazard.

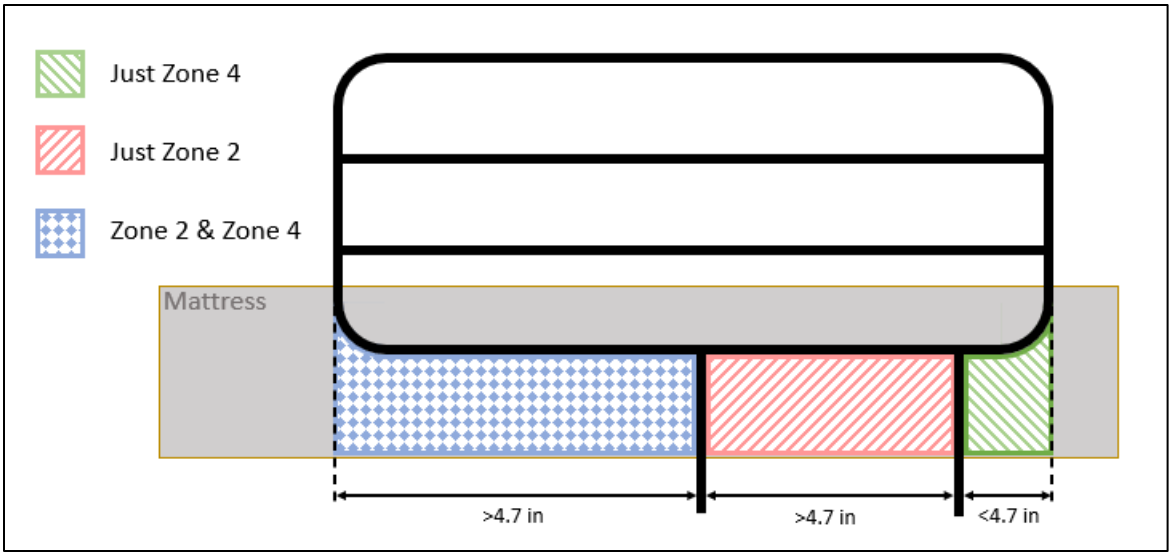


Figure 1 of Final Rule: General example of areas subject to Zone 2 requirements.

Safety testing should represent known hazard modes, including the displacement caused by consumers moving or pushing into the mattress or product, which may create an opening that was not previously visible. During entrapment zone testing, the positioning and application of the force via a force gauge must be realistic and representative of all reasonably foreseeable scenarios of consumer behavior. In many cases, applying the force to the probe by attaching a force gauge below the bottom of the rail is the most accurate representation of the worst case of this foreseeable hazard scenario. Additionally, in contrast to the current voluntary standard, entrapment hazards are not present only in the "largest opening" of a product. Entrapment hazards may exist in several areas depending on the product configuration and installation. To ensure entrapment hazards are adequately addressed, products must be assessed in all areas that may constitute an entrapment zone. Therefore, in response to this comment, the Commission has revised the language in the final rule as follows:

- Adding a global definition for "Entrapment Zone" to the draft rule, which will clarify what areas must be tested.

- Removing language from the test methodology that may have led test personnel to unnecessarily restrict locations and orientations of the placement of the entrapment test probe for testing.
- Improving instructions for test personnel to apply forces in a manner that is more representative of the entrapment hazards.

F. Removing Mattress Thickness Selection for Testers

Comment: Louis A. Ferreira, representing Stander, suggests that the proposed addition of Section 7.1.3 of the NPR's proposed rule to the voluntary standard's requirements is not reasonably necessary to prevent or reduce an unreasonable risk of injury. Staff's proposal for this additional section would allow testers to select for testing a mattress that is up to 1.5 in. (38 mm) thicker or thinner than the range specified by the manufacturer. Standard asserts that "there is no evidence in the record that a consumer has ever suffered an injury because they used an adult bed rail on the wrong size mattress."

Response: Mattress thickness has a direct bearing on the entrapment hazard. ASTM F3186-17 defines Zones 2, 3, and 4 in relation to the product and the mattress. A mattress that is too thin can result in larger entrapment zones, posing a greater risk of entrapment. On the other hand, an APBR used with a mattress that is too thick can lead to an APBR failing to meet the standard's structural integrity performance requirement, found in Section 6.2, which states that the top of the bed rail must extend 4 inches above the mattress.

Staff has found that most APBR models can be installed and adjusted regardless of mattress thickness, and the hazard created by using an APBR on an incompatible mattress will not be apparent to the typical consumer. Therefore, it is preferable to design out hazards rather than rely on consumers to follow warnings and instructions.

Indeed, it is foreseeable that some consumers will use APBRs with mattresses that are not within the manufacturer's recommended thickness range. During APBR testing, staff found that a mattress's true thickness typically differs from the thickness advertised by the mattress manufacturer. Consumers are unlikely to measure their mattress prior to purchasing an APBR, or they may not measure it accurately. Additionally, consumers may not have information about the mattress thickness when they purchase APBRs for use by another person, or for use on a hotel or guest bed. Finally, consumers who transfer existing APBRs to a new mattress may not take any action to ensure that the APBR is appropriate for the new mattress's thickness.

The mattress thickness variability requirements in the final rule anticipates these and similar foreseeable scenarios. The requirement covers a limited range of mattresses beyond what is advertised to account for the known hazards outside of the "compatible" range.

G. Language Modifications for Mattress Thickness Selection

Comment: Consumer Voice notes that language in the proposed modifications to the voluntary standard could potentially allow manufacturers to avoid providing consumers a recommended mattress thickness range for their products. Consumer Voice requested removing this language from the final rule.

Response: The Commission agrees with Consumer Voice. Section 9.1.1.3 of the voluntary standard requires manufacturers to list a recommended thickness range. The final rule will remove "If the manufacturer does not recommend" and other related language from the proposed additions to sections 6.2.1 and 7.1 of the voluntary standard to avoid manufacturers potentially not providing consumers a recommended mattress thickness range for their products.

H. Banning Retention Straps

Comment: Consumer Voice requested staff ban the use of straps as a means of attaching the product to a bed. Consumer Voice asserts that the use of straps to attach an APBR to a bed greatly increases the risk of improper assembly and the likelihood of harm, and that straps can stretch and become loose over time.

Response: Banning retention straps would unnecessarily restrict APBR designs. The proposed modifications to the requirements of the standard, such as the requirement for a warning on an "installation component," will adequately address known hazards associated with APBRs and increase the likelihood of consumers installing the retention strap. CPSC staff has not identified any strangulation or other hazards specifically associated with retention straps, and therefore there is not sufficient evidence to support banning retention straps.

I. Modifying the Proposed Definition of "Conspicuous"

Comment: Consumer Voice expressed concerns that the proposed definition of "conspicuous," adopted from Section 3.1.3 of the voluntary standard, is too narrow. Consumer Voice suggests modifying the proposed definition in the voluntary standard to increase the requirements for visibility of warning labels on the product. Specifically, Consumer Voice recommends that the definition be revised so that "conspicuous" labels/components be visible to both the consumer and a person standing near the unit from at least two different positions.

Response: The definition of "conspicuous" in section 3.1.3 requires certain labels to be visible from one position rather than 2 positions, as proposed by the commenter. The commenter's recommended alternative definition does not provide sufficient guidance regarding the two positions in which warning labels would be required to be visible, and it could foreseeably be interpreted such that two viewing positions are only marginally different.

Therefore, the commenter's proposed definition of "conspicuous" does not represent a substantive improvement to safety.

J. Adding "Conspicuous" to Warning Labeling Requirements

Comment: Consumer Voice recommended that the term "conspicuous" should not be deleted from the warning label placement requirements in section 9.2.7, as proposed in section 1270.2(b)(18)(i) of the NPR. Consumer Voice claimed the removal of the word would weaken the requirement and make the product less safe.

Response: The warning in section 9.2.7 of ASTM F3186 is directly related to product installation. As discussed in the NPR briefing package, the warning should draw attention to the installation component and encourage its use during installation (16 CFR part 1224, the children's bed rail standard, has this same warning requiring it to be on an "installation" component). Therefore, it is unnecessary for the warning on the product to be conspicuous in the manufacturer's recommended use position. Additionally, ASTM F3186-17 requires separate warnings that address entrapment hazards and securing the APBR to the bed that are required to be placed on a conspicuous component of the product and/or packaging/instructions. Therefore, the warning in section 9.2.7 should be on an installation component but is not required to be conspicuous for the reasons discussed above.

K. Making Compliance Testing Records Publicly Available

Comment: Consumer Voice requested an additional requirement that manufacturers provide consumers with records of compliance testing upon request.

Response: Manufacturers and importers of APBRs will be required to issue a General Certificate of Conformity (GCC) under Section 14 of the CPSA and 16 CFR part 1110 for the APBR mandatory standard. A GCC requires manufacturers or importers to certify that their

general use products comply with all applicable consumer product safety rules (or similar rules, bans, standards, or regulations) under any law enforced by the Commission for that product. A GCC must accompany the applicable product or shipment of products covered by the certificate. A manufacturer or importer must furnish the GCC to distributors or retailers. Based on the available information there is not significant evidence indicating that the commenter's proposed requirement that manufacturers also provide records of compliance testing directly to consumers will substantially decrease the known hazards related to APBRs given the existing GCC framework.

L. Reorganizing Labeling Requirements

Comment: Consumer Voice argued that the labeling and warning requirements for retail packaging, instructions, and the product labels set out in the proposed rule are confusing and contradictory. Consumer Voice specifically suggested reorganizing the labeling requirements.

Response: We do not agree with Consumer Voice's proposed change to the proposed rule. The current requirement in ASTM F3186-17, which is included in the final rule, clearly states the required location for each warning.

M. Adding Labeling Requirements for Intended Use

Comment: Consumer Voice suggested adding labeling requirements to include information about the intended use of APBRs and for whom the products are designed.

Response: APBR manufacturers should specify how their product(s) function in their instructions and on their product packaging. However, staff's familiarity with existing ABPRs' marketing, packaging, labeling, and appearance leads staff to assess that consumers are likely to understand that the products are designed for elderly users and/or adult users with

disabilities/inhibited movement, so the Commission finds that additional recommended labeling is unnecessary.

N. Adding Email Address to Contact Information Requirements

Comment: Consumer Voice argues that email is an increasingly used form of communication, and including an email will make contacting manufacturers more accessible for consumers. Consumer Voice requests that the final rule should require manufacturers to include their email address in addition to the other contact information currently required.

Response: The required contact information already in the standard is adequate for consumers to contact the manufacturer. We do not have any evidence indicating that requiring an email address will decrease known hazards related to APBR products.

O. Adding Language to Warning Statements

Comment: Consumer Voice suggests adding to the language throughout the final rule's warning statements, specifically by including a discussion of the risk of "serious injury or death from entrapment."

Response: Each warning clearly states that improper use and/or installation can lead to entrapment and death. Therefore, no change to the final rule is necessary based on this comment.

P. Adding Drawings in Instructional Literature Requirements

Comment: Consumer Voice recommends requiring manufacturers to include drawings in the instructions that depict potential examples of entrapment to allow consumers to better understand the potential hazards of APBRs.

Response: Section 11.1 of the APBR voluntary standard, ASTM F3186-17 includes a similar requirement and is incorporated by reference in the final rule. Manufacturers are

required to include drawings of all entrapment zones (zones 1-4). The FDA drawings are provided as a reference in Appendix X1.1 but manufacturers are free to use their own illustrations should they choose to do so.

Q. Stockpiling

Comment: Consumer Voice and CANHR, submitted comments in favor of the stockpiling provision proposed in the NPR. No comments objecting to the proposed stockpiling provision were submitted. Therefore, the prohibition on stockpiling will be finalized as proposed.

R. Effective Date

Comments: Three commenters submitted comments regarding the effective date. Consumer Voice and CANHR were in favor of the 30-day effective date. Louis A. Ferreira, representing Stander, urged that the rule should not prohibit Stander from selling existing stock of APBRs that are compliant with the ASTM F3186-17 standard.

Consumer Voice considered the 30-day effective date to be appropriate and fair, and stated that "manufacturers should not need more than 30 days." They also commented that the ASTM standards went into effect in 2017 and that "[f]ive years is more than enough time to understand the standards and take the steps necessary to comply." CANHR "support[ed] the staff's recommendation not to issue the new rule with an introduction time more than 30 days" while also noting that the ASTM voluntary standard has been available to manufacturers and other interested parties since 2017.

Stander states, "Stander has made a significant investment to produce product consistent with the existing ASTM Standard" and "it would require a least a year to sell its existing stock that is compliant with the existing ASTM Standard but not the modified ASTM Standard." Stander further states that "[a]s the CPSC has found that the compliance with the existing ASTM

Standard is sufficient to eliminate the 'unreasonable' risks posed by APBRs, CPSC should expressly allow manufacturers a reasonable period of time to sell existing stock that complies with the current ASTM Standard." Stander "believes that a reasonable period to sell its ASTM Standard compliant stock would be one year."

Response: No commenter contends that a 30-day period is insufficient for manufacturers to come into compliance with the final rule. However, Stander expressed concerns regarding selling their existing stock of APBRs. The final rule does not prohibit Stander from selling its existing stock that was manufactured before publication of the final rule in the *Federal Register.*

Finally, for clarity, we disagree with Stander's claim that "the CPSC has found the compliance with the existing ASTM Standard is sufficient to eliminate the 'unreasonable' risks posed by APBRs." In the NPR, the Commission preliminarily determined that the combined requirements of the voluntary standard—with the proposed modifications that were deemed necessary—would adequately reduce unreasonable risk and injury associated with APBR entrapment. 87 FR 67586. The Commission did not find the voluntary standard *by itself* sufficient to address the unreasonable risk posed by APBRs. That approach is unchanged for the final rule.

VI. Description of the Final Rule

The Commission determines that ASTM F3186-17, with modifications to improve safety, will address all known product hazard modes associated with APBRs, particularly entrapment. The provisions of the final rule are described below.

A. § 1270.1 – Scope, Application, and Effective Date

Section 1270.1 provides that new part 1270 establishes a consumer product safety standard for APBRs manufactured after the effective date of the final rule. This section is being finalized as proposed.

B. § 1270.2 – Requirements for Adult Portable Bed Rails

Section 1270.2 of the final rule sets forth the requirements for APBRs. Section 1270.2(a) requires each APBR to comply with all applicable provisions of ASTM F3186-17. Section 1270.2(a) is being finalized as proposed.

Section 1270.2(b) provides the requirements for APBRs in addition to those based on ASTM F3186-17. Most of the requirements of section 1270.2(b) are being finalized as proposed in the NPR. Detailed descriptions and justifications for the proposed requirements can be found in the preamble of the NPR and the staff briefing package for the NPR. Several provisions of proposed section 1270(b) have been revised in the final rule in response to comments. For additional information regarding the comments that resulted in changes to the final rule and a detailed summary of the comments and responses see Section V. of this preamble and the staff briefing package for the final rule. Below is a description of the changes made from the proposed rule to the final rule. In addition to the changes described below to the final rule, non-substantive conforming, editorial edits, and changes to numbering and cross references were made in the final rule for consistency and accuracy.

1. § 1270(b)(1)

A comment from APBR seller Stander, indicated that the proposed rule is ambiguous regarding the testing of entrapment zones. ASTM F3186-17 does not define the term "Entrapment Zone." The preamble of the NPR referenced both the FDA guidance document and incident data to explain how the entrapment zones will be identified, and the different ways

entrapment can occur within the entrapment zones. However, adding a global definition for "Entrapment Zone" to the final rule will clarify what areas must be tested. Therefore, section 1270(b)(1)(i) of the final rule includes a new definition for "entrapment zone," which is defined as "An area, gap, or opening that can potentially capture or restrain a person's body part. Hazardous openings may not always be visible prior to testing." The three original definitions in proposed 1270(b)(1) have been renumbered from proposed 1270(b)(1)(i-iii) to 1270(b)(1)(ii-iv) in the final rule to account for the addition of the new definition of entrapment zone in section 1270(b)(1)(i) of the final rule.

2. § 1270(b)(3)

Based on Stander's comment that recommended revisions to the proposed language for mattress thickness selection, the Commission is removing from section 1270(b)(3)(i) of the final rule language that could be interpreted as exempting manufacturers from including a range of compatible mattress thicknesses, which is contradictory to the intent of the standard.

3. § 1270(b)(8)

A comment from Consumer Voice was submitted indicating that the original proposed language seems to create an alternative requirement for manufacturers that do not provide a recommended thickness range, as required by section 9.1.1.3 of the voluntary standard. Based on the comment, section 1270(b)(8)(i) of the final rule adds an additional range that will increase safety by accounting for foreseeable differences between nominal and actual mattress thicknesses, as well as consumer mattress selection that deviates from manufacturer recommendations.

4. § 1270(b)(9)

Proposed 1270(b)(9) contained the introductory instruction of "In addition to complying with section 7.2 of ASTM F3186-17", when it should have read "Instead of complying with section 7.2 of ASTM F3186-17". The final rule has been revised to correct this error.

5. §§ 1270(b)(11) and (13)

Based on a comment from Stander, the language in proposed sections 1270(b)(11)(i) and (13)(i) has been revised in the final rule to remove restrictions on how the probe and force should be applied, and thereby better represent the known hazard patterns and ensure consistent interpretations of the test methods. Applying the force perpendicular to the 2.4-inch end of the probe may not always emulate the potential hazard of head or limb entrapment. Therefore, the language in sections 1270(b)(11)(i) and (b)(13)(i) of the final rule has been revised to "in the direction most likely to lead to failure of the requirement" to make it clearer and more easily understood by safety testing personnel.

6. §§ 1270(b)(12)

Also based on a comment from Stander, section 1270(b)(12)(i) has been revised in the final rule to remove restrictions on how the probe and force should be applied to better represent the known hazard patterns. The language in section 1270(b)(12)(i) of the final rule has been revised to read "at the angle most likely to allow it to pass through" to make it clearer and more easily understood by safety testing personnel.

7. § 1270(b)(14) (Previously proposed § 1270(b)(13)(ii))

The requirements of proposed section 1270(b)(13)(ii) in the NPR have been renumbered as revised section 1270(b)(14) in the final rule. Therefore, proposed sections 1270(b)(14)-(19) have been renumbered as sections 1270(b)(15)-(20) in the final rule. Revised section 1270(b)(14) has been modified from the proposed rule because proposed 1270(b)(13) incorrectly

states that the language "Instead of complying with [the applicable ASTM provision]" applies to both subsections 1270(b)(13)(i) and (ii). The introductory instructional sentence for proposed section 1270(b)(13)(ii) should read "In addition to complying with [the applicable ASTM provision]." Therefore, in the final rule section 1270(b)(14)(i) has been revised to provide the correct introductory instruction for proposed 1270(b)(13)(ii).

Additionally, section 1270(b)(14)(i) in the final rule has been revised from proposed 1270(b)(13)(ii). Stander raised concerns about the location of Zone 2 on bed rails with multiple supports. Zone 2 testing is meant to address head-first entry under the rail into any opening between the mattress compressed by the weight of a consumer's head and a section of the bedrail. Bed rails that have overhanging elements longer than 4.7 inches can allow the passage of the head in a manner consistent with identified Zone 2 entrapment hazards regardless of the number or location of vertical support rails. 4.7 inches is the diameter of the test probe and encompasses the 5th percentile female head breadth. Therefore, revised section 1270(b)(14)(i) clarifies which areas should be included in Zone 2 testing along with adding a new figure 1 illustration that visually depicts the clarifying language.

C. § 1270.3 – Prohibited Stockpiling

In the NPR, the Commission proposed an anti-stockpiling provision to prevent firms from manufacturing large quantities of non-compliant APBRs before the rule takes effect. This section makes it a prohibited act, for the period of time between the date of *Federal Register* publication of the final rule and the effective date of the final rule, for manufacturers and importers to manufacture or import APBRs at a rate that is greater than 105 percent of the rate at which they manufactured or imported APBRs during the base period of sales for the manufacturer or importer. The prohibited stockpiling provision is being finalized as proposed.

D. § 1270.4 – Findings

The findings required by section 9 of the CPSA are discussed throughout the preamble of this rule and set forth in section 1270.4 of the rule. While the findings in section 1270.4 have updated for the final rule, they are substantively the same as the proposed findings in the NPR.

VII. Final Regulatory Analysis

Pursuant to section 9(f)(2) of the Consumer Product Safety Act, publication of a final rule must include a final regulatory analysis containing:

- A description of the potential benefits and potential costs of the rule, including any benefits or costs that cannot be quantified in monetary terms, and an identification of those likely to receive the benefits and bear the costs.
- A description of any alternatives to the final rule which were considered by the Commission, together with a summary description of their potential benefits and costs and a brief explanation of the reasons why these alternatives were not chosen.
- A summary of any significant issues raised by the comments submitted during the public comment period in response to the preliminary regulatory analysis, and a summary of the assessment by the Commission of such issues.

A. Final Description of Potential Benefits and Costs of the Rule

Since the publication of the NPR in the *Federal Register* on November 9, 2022, the Commission has not identified any material changes in the APBR market, or in the data used in the preliminary analysis of benefits and costs. Though some of the comments on the NPR described possible economic impacts of the rule, none of the comments specifically addressed or otherwise suggested changes to the preliminary regulatory analysis. Therefore, the final regulatory analysis for the final rule discussed below is substantively unchanged from the

analysis described in the preamble of the NPR and in Tab G of the staff NPR briefing package, as explained in Tab C of the final rule briefing package.

CPSC's assessment of the final rule's potential benefits and costs is that the quantifiable benefits of the rule are in the range of $66.75 million per year (assuming a 25% efficacy rate for the rule's requirements) to $200.24 million per year (assuming a 75% efficacy rate). The costs associated with the rule's requirements to prevent the hazards associated with APBRs are expected to be $2.01 million per year. On a per product basis, the benefits of the final rule are estimated to be between $110.59 per APBR (25% efficacy) and $331.78 per APBR (75% efficacy), and the costs are estimated at $3.34 per APBR. All these amounts are in 2021 dollars using a discount rate of 3 percent. The Commission's analysis is based on incident reports for entrapments, only. Although APBRs may have been involved in other deaths or injuries, such as falls, those incidents are not considered in the benefit-cost analysis because there are limited details involving such incidents, and it is unclear what percentage, if any, of fall incidents would be prevented by the final rule.

1. Benefits of the Final Rule

The expected benefits and costs of the final rule are discussed below. The most common hazard pattern among all reported incidents is rail entrapment, accounting for more than 90 percent (284 of 310) of the fatal incidents. CPSC uses the period 2010 through 2019 for its rates of fatalities because, at the time of the NPR, it was the most recent 10-year window where all or nearly all incidents have been reported. The NPR identified 158 deaths from entrapment that occurred from 2010 through 2019. This number accounts for 92 percent of observed death incidents; the remaining 8 percent were caused by underlying incidents that may or may not be prevented by the final rule. To forecast entrapment deaths into the future, CPSC used death rates

per million APBRs in conjunction with its forecast of APBRs in use throughout the study period. The NPR assumed deaths would stay the same as the average rates observed between 2010 to 2019: 31.9 deaths per million APBRs.

To estimate the societal costs of entrapment deaths, CPSC applies the value of statistical life (VSL). VSL is an estimate used in benefit-cost analysis to place a value on reductions in the likelihood of premature deaths. The VSL does not place a value on individual lives, but rather, it represents an extrapolated estimate, based on the rate at which individuals trade money for small changes in mortality risk. CPSC specifically applies the estimate of the VSL developed by the U.S. Environmental Protection Agency (EPA). The EPA estimate of the VSL, when adjusted for inflation, is $10.5 million in 2021 dollars. CPSC multiplies the VSL by the number of forecasted deaths throughout the study period to calculate societal costs of deaths from entrapment in the absence of the final rule.

We further assume that the number of firms and ABPR models in use will tend to be stable in future years around the values in 2022: 12 firms and 65 models. The market for APBRs is expected to grow at an average rate of 2.01 percent per between 2024 and 2053 as a result of an aging U.S. population. Assuming the rate of incidents per million APBRs stays constant, an industry of this size would result in an average of 32 deaths from entrapment per year. At a VSL of $10.5 million (2021 dollars), the annualized present value of the potential benefits of the final rule is $298.11 million.

The Commission has not included non-fatal injuries in the foregoing benefit-cost assessment because for many incidents involving such injuries, there is not sufficient information to determine whether they would be prevented by the final rule. However, non-fatal injuries have been quantified and monetized in a sensitivity analysis as a potential upper limit to assess

the benefits of this final rule. Further, the requirements of the final rule are expected to address the 92 percent of deaths caused by entrapment. However, because we do not assume the final rule will eliminate all deaths caused by entrapment, we assessed potential benefits for the final rule under three scenarios, estimating benefits at 75 percent, 50 percent, and 25 percent of the 92 percent baseline efficacy.

At these rates under varying conservative assumptions (i.e., likely to underestimate the benefits of the rule), CPSC estimates the annualized benefits of the final rule to be $200.24 million, $133.49 million, and $66.75 million, respectively. As discussed below, annualized costs associated with the final requirements to prevent APBR hazards are estimated to be approximately $2 million. This results in net quantifiable benefits of $198.23 million, $131.48 million, and $64.74 million on an annualized basis under these various scenarios that assume reduced benefits. Table 10 summarizes the projected benefits of the final rule.

Table 10: Benefits of the Final Rule

Benefits Discounted at 3%	Effective Rates		
	75%	50%	25%
Total Benefits (2024-2053 in $B)	$3.92	$2.62	$1.31
Annualized Benefits (in $M)	$200.24	$133.49	$66.75
Per-Unit Benefits (in $)	$331.78	$221.19	$110.59

2. Costs of the Final Rule

The Commission's regulatory assessment of the costs of the final rule assumes that 100 percent of manufacturers will fully redesign their APBR models to comply with ASTM F3186-17, with the final rule's modifications. Like the benefits estimation, the time span of the cost analysis covers a 30-year period that starts in 2024, which is the expected year of implementation of the final rule. This cost analysis presents all cost estimates in 2021 dollars. This cost analysis

also discounts costs in the future and uses a 3 percent discount rate to estimate their present value.

The cost of implementing APBR requirements to address entrapment hazards includes the costs manufacturers incur to redesign existing models and produce new designs to comply with the final rule, as well as any additional cost of producing the APBR that is associated with its redesign. Manufacturers would likely incur expenditures in design labor, design production, design validation, and compliance testing. CPSC staff's review indicates that once existing models have been redesigned with a working solution, new models can adapt the solution at a minimal cost.

Manufacturers can transfer some, or all, of the increased production cost to consumers through price increases. In the first year, the Commission expects producer manufacturing costs to increase by $5.40 per APBR, of which $4.00 per APBR is expected to be passed on to the consumer in the form of higher prices. At the margins, some producers may exit the market because their increased marginal costs now exceed the increase in market price. Likewise, a fraction of consumers would now probably be excluded from the market because the increased market price exceeds their personal price threshold for purchasing an APBR. Deadweight loss is the measure of the losses faced by marginal producers and consumers who are forced out of the market due to the new requirements of the final rule. Table 11 summarizes the projected costs of the final rule:

Table 11: Total Cost of the Final Rule

Costs of Proposed Rule	Total Cost ($M)	Present Value ($M)
Cost of Redesigning Existing Models	$2.75	$2.59
Cost of Production of Redesigned APBRs	$60.43	$35.65
Deadweight Loss	$2.07	$1.23

3. Net Benefits of the Final Rule

Table 12 displays net benefits (difference between benefits and costs) and the benefit-cost ratio (benefits divided by costs) to assess the cost-benefit relationship of the final rule. The table displays these metrics using annualized benefits for the three scenarios: 75 percent, 50 percent, and 25 percent efficacy rates. These metrics show the draft final rule's benefits well exceed costs in each scenario.

Table 12: Annualized Net Benefits of Final Rule

Annualized Net Benefits ($M, Discounted at 3%)	Portion of Benefits Achieved over the Baseline Efficacy Rate of Redesigned APBRs		
	75%	50%	25%
Benefits	$200.24	$133.49	$66.75
Costs	$2.01	$2.01	$2.01
Net Benefits (Benefits-Costs)	$198.23	$131.48	$64.73
B/C Ratio	99.45	66.30	33.15

Table 13 compares the benefits and costs on a per-unit basis, to add a marginal value perspective. These metrics again show the final rule's benefits well exceed costs in each scenario.

Table 13: Per-APBR Net Benefits of the Final Rule

Per Unit Net Benefits ($, Discounted at 3%)	Portion of Benefits Achieved over the Baseline Efficacy Rate of Redesigned APBRs		
	75%	50%	25%
Benefits	$331.78	$221.19	$110.59
Costs	$3.34	$3.34	$3.34
Net Benefits (Benefits-Costs)	$328.45	$217.85	$107.26
B/C Ratio	99.45	66.30	33.15

B. Voluntary Standard

Based on staff's evaluation of ASTM F3186-17, the Commission determines that ASTM F3186-17, with appropriate modifications, will address the entrapment hazard presented by APBRs. As discussed in the preamble of the NPR, and Tabs C and D of both the staff's NPR

briefing package and the staff's final rule briefing package, CPSC staff collected sample populations of APBR models and tested them, first in 2018 through 2019, and then again in 2021. In each instance, all APBRs examined by staff failed to comply with one or more substantive requirements of ASTM F3186-17.

CPSC staff also conducted informal interviews with five firms in January and February 2018, to determine if the firms were familiar with the ASTM standard, if they believed their products conformed to the standard, and if they believed other suppliers would conform to the standard. Four firms indicated they were familiar with the standard; one stated that their products already conformed; two indicated some modifications were required to bring their products into compliance; and two expressed uncertainty as to whether they would put warning labels required by the voluntary standard on their product. One firm expressed concern that if they applied the required warnings to their product and competitors did not, then consumers would believe their products were more hazardous than competing APBRs without warning labels, causing the firm to lose market share.

Accordingly, CPSC testing and informal interviews showed that for the period 2018-2021 there was not substantial industry compliance with the voluntary standard. Furthermore, substantial future industry compliance is unlikely because firms have had several years to comply with the voluntary standard and, despite repeated outreach and testing, no APBRs are known to comply with all the requirements in the voluntary standard.

C. Alternatives to the Final Rule

The Commission considered six alternatives to the final rule adopted here: (1) take no regulatory action; (2) continue to conduct recalls of APBRs instead of promulgating a rule; (3) conduct an educational campaign instead of promulgating a rule; (4) ban APBRs from the

market; (5) require enhanced safety warnings without other requirements; and (6) implement the rule with a later effective date. The Commission finds that none of these alternatives would adequately address the hazards associated with APBRs.

1. No Regulatory Action

If the Commission opted to take no regulatory action, the industry foreseeably would continue in its current state, and consumers would remain at risk of entrapment and strangulation from APBRs. Rates of injuries and deaths would likely increase with the use of APBRs over time, and the estimated $298.11 million average annualized societal costs would continue to be incurred by consumers in the form of deaths and injuries. Therefore, the Commission does not find this alternative would address the unreasonable risk of injury associated with APBRs.

2. Conduct Recalls Instead of Promulgating a Final Rule

The Commission could seek voluntary or mandatory recalls of APBRs that present a substantial product hazard. With this alternative, manufacturers could continue producing noncompliant products without incurring any additional costs to modify or test APBRs for compliance with the final rule. Furthermore, recalls only apply to an individual manufacturer and product, but do not extend to similar hazardous products. Recalls also occur only after consumers have purchased and used such products with possible resulting deaths or injuries due to exposure to the hazard. Additionally, recalls can only address products that are already on the market but do not directly prevent unsafe products from entering the market. Recalls have removed several APBR models from the U.S market since 2021. However, despite these efforts, APBR sales volume remains at, or near, the 2020 pre-recall level and non-compliant APBRs remain widely available for purchase, which is to be expected given the APBR market's low barriers to entry. Therefore, a significant portion of the estimated $298.11 million average

annualized societal costs would likely continue to be incurred by consumers in the form of deaths and injuries. Further, even if recalls had reduced the size of the APBR market or the share of the market comprised of non-compliant APBRs, staff assesses the rule's benefits still would exceed the rule's costs. The final rule provides significant benefits that far exceed costs even if the draft final rule is only 75%, 50% or 25% effective. Therefore, the Commission does not find this alternative would address the unreasonable risk of injury associated with APBRs.

3. Conduct Education Campaigns

The Commission could issue press releases or use marketing techniques to warn consumers about the entrapment and strangulation hazards associated with APBRs, instead of issuing a mandatory rule. Information and marketing campaigns may reduce the number of injuries and societal costs associated with APBR entrapment and strangulation hazards. However, marketing campaigns have historically been less effective than designing the hazard out of the product or guarding the consumer from the hazard in the first instance. Information and marketing campaigns warning customers of APBR entrapment and strangulation hazards are not likely to be as effective in reducing the risk of injury as the final rule. Therefore, the Commission does not find this alternative would adequately address the unreasonable risk of injury associated with APBRs.

4. Ban APBRs from the Market

The Commission could ban APBRs under CPSA section 8. Staff weighed quantifiable and unquantifiable factors concerning the utility of APBR use in making a recommendation regarding this alternative. The use of APBRs provides many unquantifiable benefits to users, including mobility, ease of access to beds, protection against falls, and the potential for at-home care. If the Commission promulgated a rule banning APBRs, the benefits from reduced deaths

and injuries would be similar to this final rule, or potentially even greater. However, the value of individual users' lost utility could outweigh the incremental benefits of this approach. Considering both the quantifiable and unquantifiable costs and benefits, staff assessed that the net benefits of this alternative are likely less than those of the final rule. In addition, under CPSA section 8, the Commission may only declare a product to be a banned hazardous product if no feasible consumer product safety standard would adequately protect the public from the unreasonable risk of injury associated with APBRs. 15 U.S.C. 2057. The Commission finds that this final rule would adequately protect the public from this risk. Therefore, the Commission does not adopt the alternative of a ban on APBRs.

5. Enhanced Safety Warnings on APBRs

The Commission could require enhanced safety warnings on APBRs. Yet the warning labels currently on APBRs have not produced the desired results of reducing entrapment and strangulation injuries and deaths. In general, safety warnings that rely on consumers to alter their behavior to avoid the hazard are less effective than designing the hazard out of the product or guarding the consumer from the hazard in the first instance. Due to the likely continued use of APBRs at similar rates and patterns of use despite warnings, much of the estimated $298.11 million average annualized societal costs would continue to be incurred by consumers in the form of deaths and injuries. Therefore, the Commission does not find this alternative would adequately address the unreasonable risk of injury associated with APBRs.

6. Later Effective Date

The Commission could issue the rule with an effective date later than the proposed 30 days, allowing APBR firms additional time to meet the requirements of the final rule. However, the APBR industry likely will be able to comply quickly with the final rule because the

modifications needed do not require extensive product redesign, and because manufacturers have long had notice of the requirements of ASTM F3186-17. Delaying implementation of the rule would allow the sale of non-compliant products for a longer period of time, which would likely result in higher social costs, in the form of fatal and non-fatal APBR entrapment injuries from products not subject to the requirements of the final rule, in exchange for a limited reduction in the cost of compliance to suppliers. In addition, no commenters stated any opposition to the 30-day effective date. Therefore, the Commission does not find this alternative would adequately address the unreasonable risk of injury associated with APBRs.

VIII. Final Regulatory Flexibility Analysis

When an agency is required to publish a notice of proposed rulemaking, the Regulatory Flexibility Act (5 U.S.C. 601-612) generally requires that the agency prepare an initial regulatory flexibility analysis (IRFA) for the NPR and a final regulatory flexibility analysis (FRFA) for the final rule. 5 U.S.C. 603, 604. These analyses must describe the impact that the rule would have on small businesses and other entities. The FRFA must contain:

(1) a statement of the need for and objectives of the rule;

(2) significant issues raised by commenters on the IRFA, the agency's assessment of those issues, and changes made to the result as a result of the comments;

(3) a response to any comments filed by the Chief Counsel for Advocacy of the U.S. Small Business Administration (Advocacy), and changes made as a result of those comments;

(4) a description and estimate of the number of small entities to which the rule will apply;

(5) a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will

be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and

(6) steps the agency has taken to minimize the significant economic impact on small entities, consistent with the objective of the applicable statute, including the factual, policy, and legal reasons for selecting the alternative in the final rule and why other alternatives were rejected.

The full regulatory flexibility analysis provided in Tab D of staff's final rule briefing package is summarized below.

A. Need For and Objective of the Final Rule

The purpose of the final rule is to reduce deaths and injuries resulting from entrapment, falls, and other APBR hazards. CPSC identified 310 fatal injuries and 1,946 nonfatal injuries associated with APBR hazards in the years 2003 through 2021. CPSC assesses compliance with the voluntary standard, ASTM F3186-17, with modifications, would substantially reduce fatal and nonfatal injuries associated with APBR hazards. Accordingly, the Commission finds that a mandatory rule is reasonably necessary to reduce the unreasonable risk of injury of entrapments from APBRs.

B. Significant Issues Raised by Comments

Seven comments were submitted in response to the NPR. Some of the comments described possible economic impacts of the rule, including economic impacts on firms, the utility of the product for consumers, costs associated with the product hazards, and alternative actions that the Commission could take. However, none of the comments specifically addressed, or resulted in changes to, the initial regulatory flexibility analysis. A summary of the significant issues with possible economic impacts and a summary of staff's assessment of such issues is

contained in section V of the preamble and in the Appendix to Tab C of the staff's briefing package for the final rule. The Chief Counsel for Advocacy of the Small Business Administration did not file a comment on the NPR.

C. Small Entities to Which the Rule Will Apply

The final rule will apply to all manufacturers and importers of APBRs. CPSC has identified seven U.S. APBR manufacturers that meet the SBA criteria for small businesses. Importers of APBRs could be wholesale or retail distributors. CPSC identified one U.S. APBR firm in these categories that could be considered a small business.

D. Compliance, Reporting, and Record-Keeping Requirements of Final Rule

The final rule establishes a performance requirement for APBRs and test procedures that suppliers would have to meet to sell APBRs in the United States. Specifically, the final rule requires APBRs sold in the United States to comply with the ASTM F3186-17 standard, with modifications. CPSC expects most APBR manufacturers, including those considered small by SBA standards, would incur costs associated with bringing their APBRs into compliance with the final rule, as well as costs related to testing and issuing a GCC.

In accordance with Section 14 of the CPSA, manufacturers would have to issue a GCC for each APBR model, certifying that the model complies with the final rule. According to Section 14(a)(1) of the CPSA, GCCs must be based on a test of each product, or a reasonable testing program; and GCCs must be provided to all distributors or retailers of the product. The manufacturer would have to comply with 16 CFR part 1110 concerning the content of the GCC, retention of the associated records, and all other applicable requirements.

E. Impact on Small Entities

Generally, CPSC considers an impact to be potentially significant if it exceeds 1 percent of a firm's gross revenue. The initial cost to comply with the final rule appears to exceed 1 percent of reported annual revenue for 3 of the 7 manufacturers identified as small businesses. For these 3 APBR manufacturers, the economic impact of the proposed rule is expected to be significant. As discussed in Tab D of staff's final rule briefing package, to achieve compliance with the final rule's performance requirements, APBR suppliers would incur costs from redesigning, retooling, and testing. CPSC staff estimates this cost to be $42,239 per model in the first year. Staff estimates the additional production cost for labor and material to be $5.40 per unit produced in the first year, of which $4.00 is expected to be passed on to the consumer. CPSC has identified one possible importer of APBRs from foreign suppliers that would be considered small businesses based on SBA size standards. For this small importer, the cost of certification testing is unlikely to exceed 1 percent of annual revenue. Additionally, the foreign manufacturers are likely to provide a GCC certification on which the small importer can rely. Furthermore, given that the APBR industry is expected to continue to grow, CPSC does not anticipate foreign manufacturers exiting the industry because of the implementation of the final rule. Therefore, the final rule will not have a significant economic impact on APBR importers.

F. Other Significant Alternatives to the Rule Considered

Section VII.C. Regulatory Analysis of this preamble provides a detailed discussion of six alternatives to the final rule that were considered and why those alternatives were rejected. While the alternatives could reduce the burden on small entities, none of the alternatives are consistent with achieving the rule's objective of improving consumer safety by protecting consumers from entrapment by APBRs.

IX. Incorporation by Reference

The Commission is incorporating by reference ASTM F3186-17, *Standard Specification for Adult Portable Bed Rails and Related Products*. The Office of the Federal Register (OFR) has regulations regarding incorporation by reference. 1 CFR part 51. Under these regulations, agencies must discuss, in the preamble to a final rule, ways in which the material the agency incorporates by reference is reasonably available to interested parties, and how interested parties can obtain the material. In addition, the preamble to the final rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR regulations, Section IV. of this preamble summarizes the major provisions of ASTM F3186-17 that the Commission incorporates by reference into 16 CFR part 1270. The standard itself is reasonably available to interested parties. Until the final rule takes effect, a read-only copy of ASTM F3186-17 is available for viewing, at no cost, on ASTM's website at: https://www.astm.org/CPSC.htm. Once the rule takes effect, a read-only copy of the standard will be available for viewing, at no cost, on the ASTM website at: https://www.astm.org/READINGLIBRARY/. Interested parties can also schedule an appointment to inspect a copy of the standard at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, telephone: (301) 504-7479; e-mail: cpsc-os@cpsc.gov. Interested parties can purchase a copy of ASTM F3186-17 from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959 USA; telephone: (610) 832-9585; www.astm.org.

X. Paperwork Reduction Act

This 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 (PRA; 44 U.S.C. 3501–3521). The preamble to the NPR discussed the information

collection burden of the proposed rule and specifically requested comments on the accuracy of CPSC's estimates. 87 FR 67586 (Nov. 9, 2022). The NPR described the provisions of the proposed rule and provided an estimate of the annual reporting burden for the rule under the PRA. *See* 87 FR at 67605. The estimated burden of this collection of information is unchanged from the NPR. CPSC did not receive any comments regarding the information collection burden in the NPR through OMB. OMB has assigned control number 3041-0192 to this information collection.

XI. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of a final rule. 5 U.S.C. 553(d). Section 9(g)(1) of the CPSA states that a consumer product safety rule shall specify the date such rule is to take effect, and that the effective date must be at least 30 days after promulgation but cannot exceed 180 days from the date a rule is promulgated, unless the Commission finds, for good cause shown, that a later effective date is in the public interest and publishes its reasons for such finding.

The Commission proposed in the NPR an effective date of 30 days after publication of the final rule in the *Federal Register*. The Commission received no negative comments on the proposed effective date and has determined the proposed 30-day effective date is appropriate and will be finalized as proposed. ASTM F3186-17 has been in existence since August 2017, and agency staff has conducted outreach efforts to make firms aware of the requirements of the standard. Accordingly, manufacturers already are familiar with the requirements of ASTM F3186-17 and should be ready and able to comply with the requirements included in the final rule. The rule applies to all APBRs manufactured after the effective date.

XII. Certification

As discussed in Section VIII.D. of this preamble, in accordance with Section 14 of the CPSA manufacturers would have to issue a GCC for each APBR model, certifying that the product complies with the final rule.

XIII. Preemption

Executive Order 12988, Civil Justice Reform (Feb. 5, 1996), directs agencies to specify the preemptive effect of a rule. 61 FR 4729 (Feb. 7, 1996). The rule for APBRs is issued under the authority of the CPSA. 15 U.S.C. 2051-2089. Section 26 of the CPSA provides that "whenever a consumer product safety standard under this Act is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal Standard." 15 U.S.C. 2075(a). Thus, the final rule for APBRs preempts non-identical state or local requirements for APBRs that are designed to protect against the same risk of injury.

States or political subdivisions of a state may apply for an exemption from preemption regarding a consumer product safety standard, and the Commission may issue a rule granting the exemption if it finds that the state or local standard: (1) provides a significantly higher degree of protection from the risk of injury or illness than the CPSA standard; and (2) does not unduly burden interstate commerce. *Id.* 2075(c).

XIV. Environmental Considerations

Generally, the Commission's regulations are considered to have little or no potential for affecting the human environment, and environmental assessments and impact statements are not usually required. *See* 16 CFR 1021.5(a). The final rule is not expected to have an adverse impact on the environment and is considered to fall within the "categorical exclusion" for the purposes of the National Environmental Policy Act. 16 CFR 1021.5(c).

XIV. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801-808) states that before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The CRA submission must indicate whether the rule is a "major rule." The CRA states that the Office of Information and Regulatory Affairs determines whether a rule qualifies as a "major rule."

Pursuant to the CRA, OMB's Office of Information and Regulatory Affairs has determined that this rule qualifies as a "major rule," as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General and postpone enforcement of the rule during the Congressional review period specified in the CRA.

XV. Findings

As explained, the CPSA requires the Commission to make certain findings when issuing a consumer product safety standard. 15 U.S.C. 2058(f)(1), (f)(3). These findings are stated in § 1270.4 of the rule and are based on information provided throughout this preamble and the staff's briefing packages for the proposed and final rules.

List of Subjects

16 CFR Part 1270

Administrative practice and procedure, Consumer protection, Incorporation by reference, Adult portable bed rails.

For the reasons discussed in the preamble, the Commission amends Title 16 of the Code of Federal Regulations by adding a new part to read as follows:

PART 1270—SAFETY STANDARD FOR ADULT PORTABLE BED RAILS

Sec.

Authority: 15 U.S.C. 2056, 15 U.S.C 2058, and 5 U.S.C. 553

§ 1270.1 Scope, application, and effective date.

This part 1270 establishes a consumer product safety standard for adult portable bed rails manufactured after [**insert date 30 days after date of publication of the final rule in the FEDERAL REGISTER**].

§ 1270.2 Requirements for adult portable bed rails.

(a) Except as provided in paragraph (b) of this section, each adult portable bed rail must comply with all applicable provisions of ASTM F3186-17, *Standard Specification for Adult Portable Bed Rails and Related Products*, approved on August 1, 2017. 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. A read-only copy of the standard is available for viewing on the ASTM

website at https://www.astm.org/READINGLIBRARY/. You may obtain a copy from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959; telephone (610) 832-9585; www.astm.org. You may inspect a copy from the Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504-7479, e-mail cpsc-os@cpsc.gov, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, e-mail fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html.

(b) Comply with the ASTM F3186-17 standard with the following changes:

(1) In addition to complying with the definitions in section 3.1 of ASTM F3186-17, comply with the following definitions:

(i) *Entrapment Zone*. An area, gap, or opening that can potentially capture or restrain a person's body part. Hazardous openings may not always be visible prior to testing.

(ii) *Initial Assembly.* The first assembly of the product components after purchase, and prior to installing on the bed.

(iii) *Initial Installation.* The first installation of the product onto a bed or mattress.

(iv) *Installation Component.* Component(s) of the bed rail that is/are specifically designed to attach the bed and typically located under the mattress when in the manufacturer's recommended use position.

(2) Instead of complying with section 6.1.3 of ASTM F3186-17, comply with the following:

(i) Permanently attached retention system components shall not be able to be removed without the use of a tool after initial assembly.

(ii) [Reserved]

(3) In addition to complying with section 6.2.1 of ASTM F3186-17, comply with the following:

(i) The test personnel shall choose a mattress and product setting configuration that results in the most severe condition per test requirement (see paragraph (b)(8)(i)).

(ii) [Reserved]

(4) Instead of complying with section 6.3.3 of ASTM F3186-17, comply with the following:

(i) *Zone 3*—When tested in accordance with § 8.4.5, the horizontal centerline on the face of the 4.7 in (120 mm) end of the test probe (see paragraph (b)(9)(i)) shall be above the highest point of the uncompressed mattress.

(ii) [Reserved]

(5) Instead of complying with section 6.4.1 of ASTM F3186-17, comply with the following:

(i) Holes or slots that extend entirely through a wall section of any rigid material less than 0.375 in (9.53 mm) thick and admit a 0.210 in (5.33 mm) diameter rod shall also admit a 0.375 in (9.53 mm) diameter rod. Holes or slots that are between 0.210 in (5.33 mm) and 0.375 in (9.53 mm) and have a wall thickness less than 0.375 in (9.53 mm) but are limited in depth to 0.375 in (9.53 mm) maximum by another rigid surface shall be permissible (see Opening Example in Figure 2 of ASTM F3186-17).

(ii) [Reserved]

(6) Instead of complying with section 6.5.1 of ASTM F3186-17, comply with the following:

(i) Any structural components and retention system components of a product covered by this specification that require consumer assembly or adjustment, or components that may be removed by the consumer without the use of a tool, shall not be able to be misassembled when evaluated to (see paragraph (b)(7)(i)).

(ii) [Reserved]

(7) Instead of complying with section 6.5.2 of ASTM F3186-17, comply with the following:

(i) *Determining Misassembled Product:* A product covered by this specification shall be considered misassembled if it appears to be functional under any condition and it does not meet the requirements of 6.1–6.4.

(ii) [Reserved]

(8) In addition to complying with section 7.1 of ASTM F3186-17, comply with the following:

(i) Mattress thickness ranges used for testing shall be up to 1.5 in. (38 mm) larger or smaller than the range specified by the manufacturer. Test personnel shall choose a mattress and product setting configuration that provide the most severe condition for each test requirement in the standard. **NOTE 1 to paragraph (b)(8)(i)**: The technology and consumer preferences for bedding are highly variable and continuously changing. Therefore, they cannot be reasonably accounted for within this standard. Test facilities and personnel should consider current bedding trends and all types of mattresses that may foreseeably be used with the product when making a test mattress selection.

(ii) [Reserved]

(9) Instead of complying with section 7.2 of ASTM F3186-17, comply with the following:

(i) *Entrapment test probe.* The test probe shall be as described in the FDA Guidance Document, "*Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment*," which can be found at: www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment. The test probe can be independently manufactured per the dimensional constraints in the guidance document or purchased from Bionix, 5154 Enterprise Blvd, Toledo, OH 43612, 800-551-7096, www.bionix.com. Videos illustrating use of the test probe are available at: www.youtube.com/c/BionixLLC/search.

(ii) [Reserved]

(10) Instead of complying with Note 1 in section 8.4 of ASTM F3186-17, comply with the following:

NOTE 1 to paragraph (b)(10): The tests described in this section are similar to those described in the referenced FDA Guidance Document.

(11) Instead of complying with section 8.4.3.4 of ASTM F3186-17, comply with the following:

(i) If the test probe does not pull through freely, attach the force gauge and exert a 22.5 lbf (100 N) pulling force to the 2.4 in (60 mm) cylindrical end of the entrapment test probe in the direction most likely to lead to failure of the requirement. If the 4.7 in (120 mm) end of the cone does not enter any of the openings, this space passes the test. If the 4.7 in (120 mm) end of the test probe cone does enter any of the openings, this space fails the test.

(ii) [Reserved]

(12) Instead of complying with section 8.4.4.3 of ASTM F3186-17, comply with the following:

(i) Insert the 2.4 in (60 mm) end of the cone into the opening at the angle most likely to allow it to pass through. Insert the cone into the opening until it is in full contact with the product. The mattress shall only be compressed by the weight of the cone.

(ii) [Reserved]

(13) Instead of complying with section 8.4.4.4 of ASTM F3186-17, comply with the following:

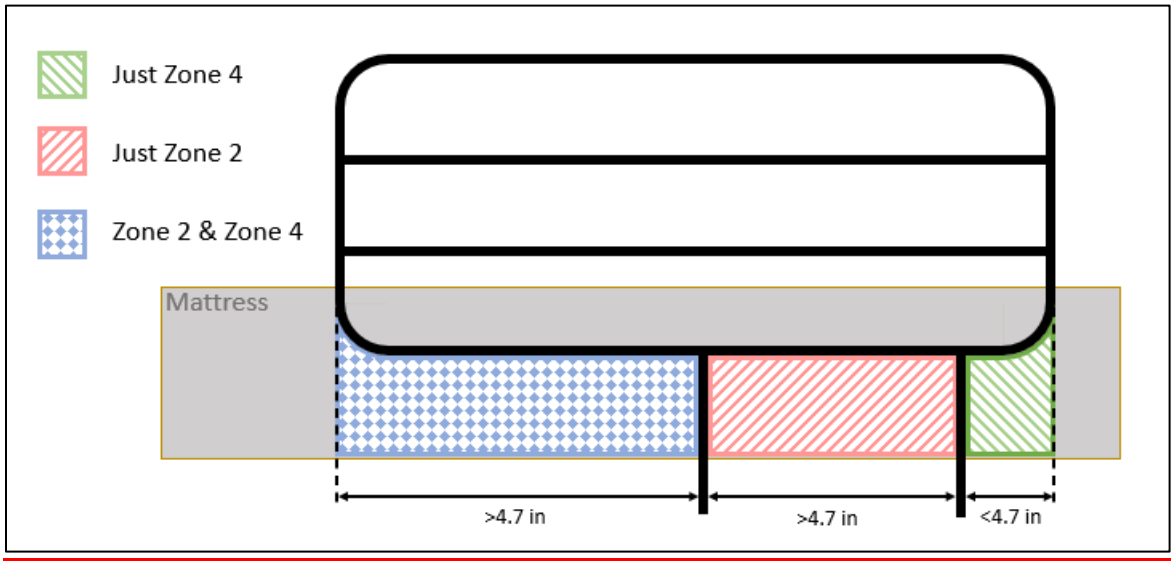
(i) If the test probe does not pull through freely use the force gauge to exert a 22.5 lbf (100 N) pulling force to the 2.4 in (60 mm) cylindrical end of the cone in the direction most likely to lead to failure of the requirement.

(ii) [Reserved]

(14) In addition to complying with section 8.4.4 of ASTM F3186-17 comply with the following:

(i) If a horizontal section of the rail greater than 4.7 in exists along the bottom of the rail, that section must also meet the Zone 2 requirements regardless of the number or location of the supports. Repeat testing described in sections 8.4.4.3 (see paragraph (12)(i)) and 8.4.4.4 (see paragraph (13)(i)) for all applicable entrapment zones. Figure 1 below shows a general example of areas subject to Zone 2 requirements.

Figure 1: General example of areas subject to Zone 2 requirements.



(ii) [Reserved]

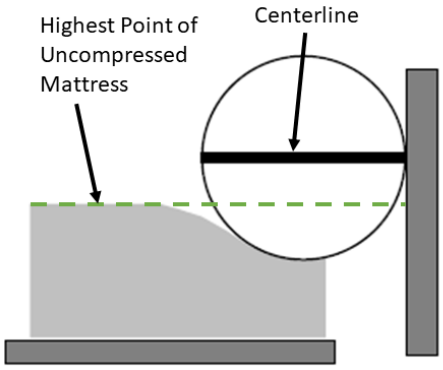
(15) Instead of complying with section 8.4.5.4 of ASTM F3186-17, comply with the following:

(i) Turn the cone until the line on the face of the 4.7 in (120 mm) end is horizontal and let the cone sink into the space by its own weight.

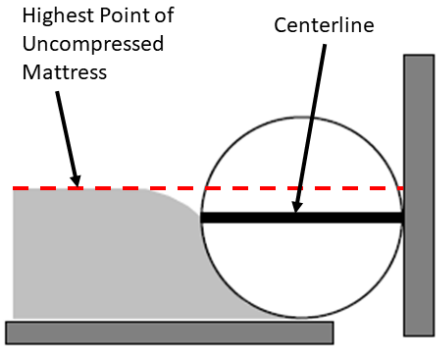
(A) If the line on the face of the 4.7 in (120 mm) end of the cone is above the highest point of the uncompressed mattress, as shown in Figure 2 to paragraph (b)(15) of this section, the space passes the test.

(B) If the line on the face of the 4.7 in (120 mm) end of the cone is at or below the highest point of the uncompressed mattress, as shown in Figure 2 to paragraph (b)(15) of this section, the space fails the test.

Figure 2 to paragraph (b)(15) of this section: Zone 3 test: (a) Pass, (b) Fail



a: Zone 3 **Pass** Criteria
(Centerline **above** highest point of uncompressed mattress)



b: Zone 3 **Fail** Criteria
(Centerline **below** highest point of uncompressed mattress)

(ii) [Reserved]

(16) In addition to complying with section 8.6.3 of ASTM F3186-17, comply with the following:

Note 1 to Paragraph (b)(16): The "free end" is defined as the location on the retention system that is designed to produce a counter force; it may be a single distinct point or a location on a loop.

(ii) [Reserved]

(17) Instead of complying with section 9.1.1.3 of ASTM F3186-17, comply with the following:

(i) That the product is to be used only with the type and size of mattress and bed, including the range of thickness of mattresses, specified by the manufacturer of the product. If beds with head or footboards are allowed, the distance between the head or footboard and the placement of the product shall be indicated to be >12.5 in (318 mm).

(ii) [Reserved]

(18) Instead of complying with section 9.2.5 of ASTM F3186-17, comply with the following:

(i) Each product's retail package and instructions shall include the following warning statements Figure 3 to paragraph (b)(18)(i) of this section.

Figure 3 to paragraph (b)(18)(i): Warning Statements for Product Retail Package and Instruction

⚠WARNING
ENTRAPMENT, STRANGULATION, SUFFOCATION AND FALL HAZARDS
Gaps in and around this product can entrap and kill. People with Alzheimer's disease or dementia, or those who are sedated, confused, or frail are at increased risk of entrapment and strangulation. People attempting to climb over this product are at increased risk of injury or death from falls. Always make sure this product is properly secured to bed. If product can move away from bed or mattress, it can lead to entrapment and death.

(ii) [Reserved]

(19) Instead of complying with section 9.2.7 of ASTM F3186-17, comply with the following:

(i) At least one installation component of the product must be labeled with the following entrapment warning in Figure 4 to paragraph (b)(19)(i).

Figure 4 to paragraph (b)(19)(i): Entrapment Warning

⚠WARNING – ENTRAPMENT HAZARD
NEVER use product without properly securing it to bed. Incorrect installation can allow product to move away from mattress, bed frame and/or head or foot boards, which can lead to entrapment and death.

(ii) [Reserved]

(20) Instead of complying with section 11.1.1.3 of ASTM F3186-17, comply with the following:

(i) In addition to contacting the manufacturer directly, consumers can report problems to the CPSC at its website SaferProducts.gov or call 1-800-638-2772, or to the FDA at 1-800-332-1088.

(ii) [Reserved]

§ 1270.3 Prohibited Stockpiling.

(a) *Prohibited acts.* Manufacturers and importers of adult portable bed rails (APBRs) shall not manufacture or import APBRs that do not comply with the requirements of this part between [DATE OF PUBLICATION OF FINAL RULE] and [EFFECTIVE DATE OF FINAL RULE] at a rate that is greater than 105 percent of the rate at which they manufactured or imported APBRs during the base period for the manufacturer or importer.

(b) *Base period.* The base period for APBRs is the calendar month with the median manufacturing or import volume within the last 13 months immediately preceding the month of promulgation of the final rule.

§ 1270.4 Findings.

(a) General. The CPSA requires the Commission to make certain findings when issuing a consumer product safety standard. 15 U.S.C. 2058(f). This section discusses support for those findings.

(b) Degree and Nature of the Risk of Injury. Between January 2003 and December 2021, the there were 332 incident reports concerning adult portable bed rails (APBRs) in the Consumer Product Safety Risk Management System (CPSRMS). Of these, 310 were reports of fatalities, and 22 were nonfatal. Rail entrapment is the most prevalent hazard pattern among the incidents. There were 284 fatal incidents related to rail entrapment, accounting for more than 90 percent of all fatal incidents, and 2 nonfatal incidents. Falls were the second most common hazard pattern in the incident data, accounting for 25 incidents (8 percent of all incidents). There were 23 fatalities from falls.

(c) Number of Consumer Products Subject to the Rule. An estimated 12 firms supply 65 distinct APBR models. In 2021, the number of APBRs sold was approximately 180,000 units.

(d) Need of the Public for the Products and Probable Effect on Utility, Cost, and Availability of the Product. (1) APBRs are installed or used alongside a bed by consumers to: reduce the risk of falling from the bed; assist the consumer in repositioning in the bed; or assist the consumer in transitioning into or out of the bed. Because this rule is a performance standard that allows for the sale of compliant of APBRs, it is not expected to have any impact on the utility of the product.

(2) The cost of compliance to address entrapment hazards includes the costs manufacturers incur to redesign existing models and produce new designs to comply with the mandatory standard, the cost of producing the redesigned APBR, dead weight loss. To redesign existing and new models, manufacturers would likely incur expenditures in design labor, design production, design validation, and compliance testing. CPSC estimates these costs to be $42,239 per model in the first year. Manufacturers would also incur costs to produce the redesigned APBRs, however, these costs likely closely match existing production costs and therefore incremental cost is expected to be negligible. Dead weight loss refers to the lost producer and consumer surplus from reduced quantities of APBRs sold and consumed due to rule-induced price increases. Producer surplus represents the foregone profit opportunities, meaning the amount that price exceeds marginal cost for those units no longer produced. Consumer surplus represents the foregone utility from consumption, meaning the amount that willingness to pay exceeds price for units no longer consumed. In the first year, producer manufacturing costs are expected to increase by $5.40 per APBR, of which $4.00 per APBR is expected to be passed on to the consumer in the form of higher prices. The resultant decrease in the number of APBRs sold and consumed is expected to generate a dead weight loss of less than $70,000 per year nationwide, so this rule is not expected to have any significant impact on the availability of APBRs.

(e) Any Means to Achieve the Objective of the Final Rule, While Minimizing Adverse Effects on Competition and Manufacturing. (1) The rule reduces entrapment and other hazards on APBRs while minimizing the effect on competition and manufacturing. Because the rule is based on an existing voluntary standard, and because of CPSC's outreach efforts, APBR manufacturers are generally aware of the requirements. Manufacturers can transfer some, or all, of the increased production cost to consumers through price increases. At the margins, some producers may exit the market because their increased marginal costs now exceed the increase in market price. Likewise, a very small fraction of consumers may be excluded from the market if the increased market price exceeds their personal price threshold for purchasing an APBR.

(2) The Commission considered alternatives to the final rule to minimize impacts on competition and manufacturing including: (1) take no regulatory action; (2) continue to conduct recalls of APBRs instead of promulgating a final rule; (3) conduct an educational campaign instead of promulgating a final rule; (4) ban APBRs from the market; (5) require enhanced safety warnings without other requirements; and (6) implement the rule with a longer effective date. The Commission determines that none of these alternatives would adequately reduce the risk of deaths and injuries associated with APBR entrapment and other hazards presented by APBRs.

(f) Unreasonable Risk. Incident data show 284 fatal incidents related to rail entrapment between January 2003 and December 2021. The incident data show that these incidents continue to occur and are likely to increase because APBR manufacturers do not comply with the voluntary standard and the market for ABPRs is forecast to grow. The rule establishes performance requirements to address the risk of entrapments associated with ABPRs. Given the fatal and serious injuries associated with entrapments on APBRs, the Commission finds that this rule is necessary to address the unreasonable risk of injury associated with APBRs.

(g) Public Interest. The rule addresses an unreasonable risk of entrapments and other hazards associated with APBRs. Adherence to the requirements of the rule would reduce deaths and injuries from APBR entrapment incidents; thus, the rule is in the public interest.

(h) Voluntary Standards. If a voluntary standard addressing the risk of injury has been adopted and implemented, then the Commission must find that the voluntary standard is not likely to eliminate or adequately reduce the risk of injury or substantial compliance with the voluntary standard is unlikely.

(1) The Commission determines that, absent modification, the voluntary standard is not likely to eliminate or adequately reduce the risk of injury of entrapments on ABPRs. The Commission also determines that ASTM F3186-17, with the modifications described in § 1270.2, is likely to adequately reduce the risk of injury associated with APBRs. Entrapment is the most prevalent hazard pattern among the deaths and injuries associated with APBRs. The entrapment test methods specified in the voluntary standard require products to be tested to assess the potential for entrapment in four different zones. The four entrapment zones required to be tested each address specific types of entrapment as follows: (1) head-first entry into fully bounded openings within the structure of the bed rail; (2) head-first entry under the rail into any opening between the mattress and the bed rail; (3) entry of the head into a gap between the inside surface along the length of the bed rail and the compressed mattress; (4) neck-first entrapment between the ends of the bed rail and the compressed mattress. Most of the reported entrapment fatalities involved one of the four zones listed. In 214 out of 284 fatal incidents, the entrapment location was identified and all but six of these cases occurred in one of the four zones of entrapment tested in ASTM F3186-17.

(2) The Commission determines that modifications to the voluntary standard are needed to improve safety. Such modifications include: providing additional definitions for product assembly and installation to ensure their consistent and differentiated use throughout the standard; adding requirements for manufacturers to take into account the range of mattress thicknesses to ensure safe use of the product and provide testers with additional guidance for selecting the mattress thickness during the test setup; addressing inconsistencies with stated dimensions to ensure consistent dimensional tolerances; and providing additional clarity for Zone 1 and 2 test setup and methods, additional guidance for identifying potential Zone 2 openings, and updated requirements for Zone 3 testing consistency.

(3) The Commission determines that substantial compliance with the voluntary standard is unlikely. CPSC conducted two rounds of market compliance testing to ASTM F3186-17: the first round in 2018 and 2019, the second round in 2021. In both rounds, no APBRs met all requirements of ASTM F3186-17. All products failed at least one critical mechanical requirement, such as retention strap performance, structural integrity, and entrapment. All products failed the labeling, warning, and instructional requirements.

(i) Reasonable Relationship of Benefits to Costs. (1) The benefits expected from the rule bear a reasonable relationship to its cost. The rule reduces the entrapment hazard and other hazards associated with APBRs, and thereby reduces the societal costs of the resulting injuries and deaths. The rule is expected to address the 92 percent of deaths caused by entrapment, resulting in potential societal benefits of $298.11 million. Benefits additionally were assessed under three scenarios derived from this expected efficacy, estimating benefits at: 75 percent, 50 percent, and 25 percent of their potential value. Under these three scenarios, the estimated quantifiable annualized benefits of the final rule are approximately $200.24 million, $133.49 million, and

$66.75 million, respectively. The costs associated with the final requirements to prevent the hazards associated with APBRs are expected to be approximately $2.01 million per year. On a per product basis, the estimated benefits of the final rule are approximately $331.78, $221.19, and $110.59 per APBR when assessed at 75 percent, 50 percent, and 25 percent of their potential value, respectively, and the costs are approximately $3.34 per APBR. All these amounts are in 2021 dollars using a discount rate of 3 percent. (2) The requirements of the final rule, with modifications, are expected to address 92 percent of deaths caused by entrapment. Even under the most conservative assumption that only 25 percent of the potential benefits are achieved, every $1 in costs for the market to adopt the final rule equates to approximately $33.15 in benefits to society. The estimated annualized net benefits of the final rule are approximately $198.23 million, $131.48 million, and $64.74 million, at when benefits are assessed at 75 percent, 50 percent, and 25 percent of their potential value, respectively.

(j) Least-Burdensome Requirement that Would Adequately Reduce the Risk of Injury

The Commission considered six alternatives to the final rule including: (1) take no regulatory action; (2) continue to conduct recalls of APBRs instead of promulgating a rule; (3) conduct an educational campaign without a rule; (4) ban APBRs from the market entirely; (5) require enhanced safety warnings without other requirements; and (6) implement the rule with a longer effective date. Although most of these alternatives may be a less burdensome alternative to the final rule, the Commission determines that none of the alternatives would adequately reduce the risk of deaths and injuries associated with APBRs that is addressed in the rule while still preserving the product's utility to consumers.

Dated:

_____

Alberta E. Mills,

Secretary, Consumer Product Safety Commission

United States
Consumer Product Safety Commission

Staff Briefing Package
Draft Final Rule for Adult Portable Bed Rails

June 28, 2023

For additional information, contact:

Vineed K. Dayal, P.E., Mechanical Engineer,
Adult Portable Bed Rail Project Manager,
Division of Mechanical Engineering
Directorate for Laboratory Sciences
Office of Hazard Identification and Reduction
Email: vdayal@cpsc.gov

U.S. Consumer Product Safety Commission
5 Research Place
Rockville, MD 20850

This report was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

Executive Summary

Staff prepared this draft final rule (FR) briefing package that recommends finalizing the U.S. Consumer Product Safety Commission's (Commission or CPSC) notice of proposed rulemaking (NPR) to require that Adult Portable Bed Rails (APBRs) meet the requirements of ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*, with modifications. Consistent with sections 7 and 9 of the Consumer Product Safety Act (CPSA), this briefing package includes staff's response to comments received on the NPR, proposed language to modify and adopt ASTM F3186 – 17 into a regulation, a final regulatory analysis for APBRs, and a final regulatory flexibility analysis under the Regulatory Flexibility Act.

Background

On June 4, 2013, Petition CP 13-1, *Petition Requesting a Ban or Standard for Adult Portable Bed Rails* (Petition), was docketed. The Petition was based on two requests regarding APBRs sent to the Commission from several consumer advocates on April 25, 2013, and May 9, 2013. The Petition requested that CPSC consider rulemaking under the CPSA to address hazards associated with APBRs, such as entrapments, strangulations, and falls. Staff independently verified the petitioners' reported hazard modes and then worked with ASTM International to develop a voluntary standard, which was published in 2017 as ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*.

After the standard was published, the Commission directed staff to assess the effectiveness of the new standard. From 2018 through 2019, staff conducted a comprehensive analysis. Staff presented the results of the assessment to the Commission in July 2020, noting that staff had found no APBRs on the market that complied with the ASTM voluntary standard. Staff noted, however, that some of the samples tested may not have been manufactured after the voluntary standard was issued and firms may not have had enough time to adopt the voluntary standard, so an additional round of testing was completed in 2021. Staff's second round of testing concluded once again that no APBRs on the market complied with the voluntary standard, despite the facts that the voluntary standard had by then been in existence for over four years and that staff had engaged in repeated outreach efforts urging manufacturers to comply with the voluntary standard during this time period. Therefore, staff concluded that substantial compliance in the future would be unlikely without a mandatory standard.

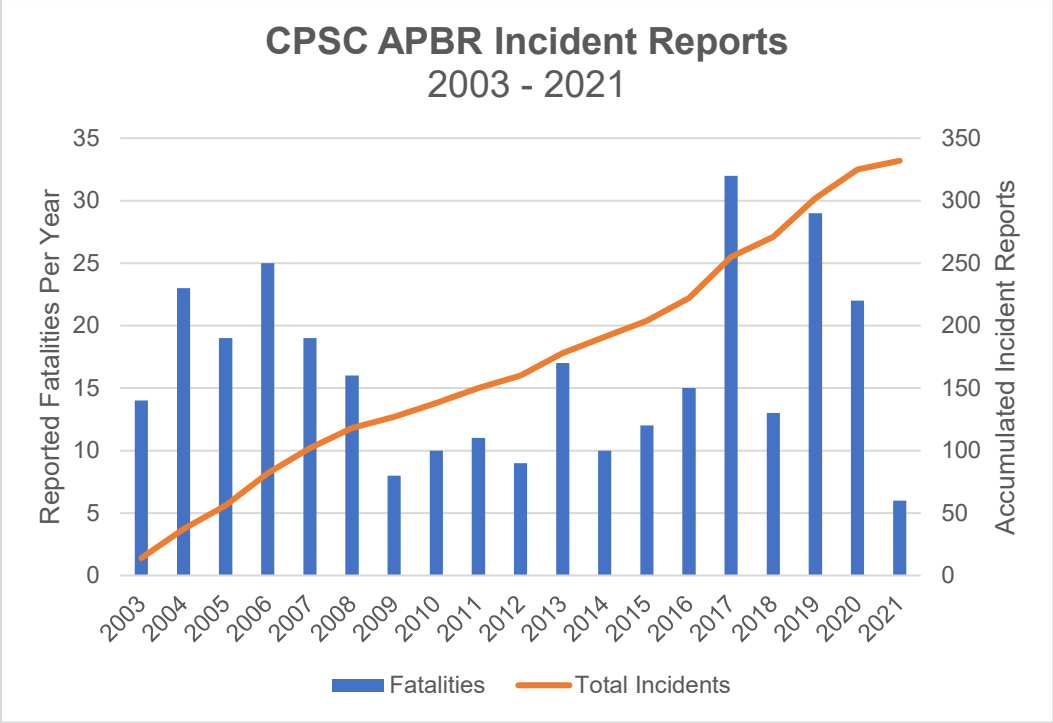
On March 9, 2022, staff sent a Petition briefing package to the Commission with staff's recommendation that the Commission grant the Petition. On March 15, 2022, the Commission voted unanimously (4-0) to grant petition CP 13-1 and directed staff to draft an NPR briefing package.

On September 21, 2022, staff submitted a draft NPR briefing package for APBRs to the Commission which was approved by Commission vote. The Commission published an NPR in the *Federal Register* on November 9, 2022, 87 Fed. Reg. 67,586. The NPR requested comments on a proposal to incorporate by reference the voluntary standard ASTM F3186 – 17, with specified modifications, to address injuries and fatal entrapment incidents associated with

APBRs. The 60-day public comment period for the NPR closed on January 9, 2023. CPSC received seven written comments and no requests for oral comments during the comment period.

Staff's Final Rule Analysis

As of April 15, 2022, CPSC had received 332 incident reports related to APBRs, with reported incidents occurring between January 2003 and December 2021. Nearly all the incidents, 310 out of 332, were fatal. In addition, staff estimates that between January 2003 and December 2021, there were 79,500 APBR-related injuries treated in hospital emergency departments across the United States. Staff concludes that most victims affected by APBRs that present an unreasonable risk of injury are members of vulnerable populations, including the elderly and people with medical conditions. Annually, there are at least 17 fatalities and over 4,200 nonfatal injuries related to APBR entrapments and strangulations. The graph below summarizes fatal incident reports by year received by CPSC. CPSC's data collection continues on an ongoing basis, and it should be noted that incident numbers for the latest 3 years may increase due to future reporting.



Staff's economic analysis for this FR is based on the preliminary findings in the NPR, which conservatively indicated the potential benefits based on only reduced fatalities associated with APBR use, from adopting a regulation requiring that APBRs comply with ASTM F3186 – 17, with modifications, to have an annualized present value of $298.11 million in 2021 dollars. In contrast, annualized costs associated with the proposed requirements to prevent APBR hazards were $2.01 million in 2021 dollars. Even at a conservative 25 percent efficacy rate for the rate at which the proposed rule mitigates deaths associated with APBR entrapment, every $1 in costs

for the market to adopt the proposed APBR rule equates to approximately $33.15 in benefits to society. Considering the deaths associated with APBRs and the lack of compliance with ASTM F3186 – 17 years after its adoption, staff concludes that the potential benefits of the proposed FR significantly outweigh the potential costs.

Staff's review of the public comments led to several changes to the text for the proposed rule, but none required substantial changes to staff's preliminary regulatory analysis, the regulatory flexibility analysis, or the conclusions of the NPR. Staff found no new information that would change the conclusions of staff's previous analyses; therefore, this draft FR does not include additional technical analyses. The analyses provided in both the NPR and staff's NPR briefing package are incorporated here and shall be considered as findings for the FR briefing package.

Staff Recommendation

To reduce the risk and decrease the number of deaths, injuries, and costs to society, staff recommends that the Commission publish a FR under sections 7 and 9 of the CPSA in the *Federal Register*, with an effective date of 30 days and a stockpiling provision that prohibits firms from importing or manufacturing non-compliant products in volumes that exceed 105 percent of the median volume of the last 13 months immediately preceding the month of promulgation of the FR.

Table of Contents

Briefing Memorandum

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

TO: The Commission
Alberta Mills, Secretary

DATE: June 28, 2023

THROUGH: Austin C. Schlick, General Counsel

Jason K. Levine, Executive Director

DeWane Ray, Deputy Executive Director for Operations

FROM: Duane Boniface, Assistant Executive Director,
Office of Hazard Identification and Reduction

Vineed K. Dayal, Project Manager,
Division of Mechanical Engineering
Directorate for Laboratory Sciences

SUBJECT: Draft Final Rule for Adult Portable Bed Rails

Introduction

On March 15, 2022, the U.S. Consumer Product Safety Commission (CPSC or Commission) voted unanimously (4-0) to grant petition CP 13-1, *Petition Requesting a Ban or Standard for Adult Portable Bed Rails*, and directed staff to draft a notice of proposed rulemaking (NPR) briefing package.[1,2]

On September 21, 2022, staff submitted a draft NPR briefing package for adult portable bed rails (APBRs) to the Commission.[3] Then, on November 9, 2022, the Commission published an NPR in the *Federal Register*, 87 Fed. Reg. 67,586. The NPR requested comments on a proposal to incorporate by reference the voluntary standard ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*, with specified modifications, to address injuries and fatal entrapment incidents associated with APBRs.[4,5] The 60-day public

[1] Petition CP 13-1, *Petition Requesting a Ban or Standard on Adult Portable Bed Rails*, Public Citizen, Gloria Black, Consumer Federation of America, Consumer Voice, et al., June 4, 2013. Retrieved from: https://www.regulations.gov/document?D=CPSC-2013-0022-0001.

[2] Record of Commission Action, Commission Vote March 15, 2022. Retrieved from: https://www.cpsc.gov/s3fs-public/RCA_PetitionRequestingaBanorStandardonAdultPortableBedRails_CP13_1.pdf?VersionId=pP0nN_HbfOuxiePTbEcrYMRi2hqoUczh

[3] Staff Briefing Package, *Staff Draft Notice of Proposed Rulemaking for Adult Portable Bed Rails*, September 21, 2022. Retrieved from: https://www.cpsc.gov/s3fs-public/ProposedRuleSafetyStandardforAdultPortableBedRails.pdf?VersionId=Ypa89Iczh13C40Tq7EJRSMDZoatChf1

[4] Proposed Rule, *Safety Standard: Adult Portable Bed Rails*, Consumer Product Safety Commission, November 9, 2022. Retrieved from: https://www.regulations.gov/document/CPSC-2013-0022-0110

[5] ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*, ASTM International, West Conshohocken, PA, 2017, www.astm.org.

comment period for the NPR closed on January 9, 2023. CPSC received seven written comments and no requests for oral comments during the comment period.

This draft final rule (FR) briefing package includes staff's response to the public comments received on the NPR, updated language in response to comments for the codified text of the draft final rule, a final regulatory analysis pursuant to section 9(f)(2) of the Consumer Product Safety Act, and a final regulatory flexibility analysis pursuant to the Regulatory Flexibility Act. Staff's technical analyses in support of its recommendation can be found in the November 9, 2022 NPR and Staff's September 21, 2022 NPR briefing package. These analyses fully support the FR as well because there is no new information that would change staff's technical analysis since the publication of the NPR. This FR builds on the information in staff's briefing package for the NPR, therefore a brief overview of the previous briefing package is provided below.

Background

APBR Product Description

There are several types of bed rails available to consumers, including some bed rails that are medical devices regulated by the U.S. Food and Drug Administration (FDA).[6,7,8] Generally, bed rails under CPSC's jurisdiction include products that are not an accessory or an appurtenance to a regulated hospital bed but are installed or used alongside of a bed by consumers intended to:

- reduce the risk of falling from the bed;
- assist the consumer in repositioning in the bed; or
- assist the consumer in transitioning into or out of the bed.

The draft final rule only applies to APBRs within CPSC's jurisdiction. Figure 1 below shows four examples of types of bed rails under CPSC jurisdiction.

[6] Information on adult bed rails under FDA jurisdiction is available at: https://www.fda.gov/medical-devices/consumer-products/adult-portable-bed-rail-safety

[7] Staff's April 23, 2014 briefing package provides additional in-depth information on the jurisdiction and types of bed rails.

[8] Staff Briefing Package, *Petition CP-13-1 Requesting a Ban or Standard for Adult Portable Bed Rails*, April 23, 2014. Retrieved from: https://www.cpsc.gov/s3fs-public/pdfs/foia_PetitionCP131RequestforBanorStandardforAdultPortableBedRail.pdf.

Figure 1: General examples of APBR types – (1) Full-Length Bed Rail, (2) Bed Cane, (3) Bed Handle, and (4) Half-Length Bed Rail

Petition CP 13-1, Petition Requesting a Ban or Standard for Adult Portable Bed Rails (2013–2022)

On April 25, 2013, and May 9, 2013, CPSC received requests from two groups (collectively Petitioners) to initiate rulemaking under sections 8 and 9 of the CPSA to address reported hazards associated with APBRs. On June 4, 2013, those requests were docketed in a single petition, CP 13-1 (Petition).

After CPSC docketed the Petition, ASTM International (ASTM) formed the F15.70 subcommittee for Adult Safety Products and began developing a voluntary standard for APBRs.[9,10] On April 23, 2014, CPSC staff sent a briefing package to the Commission, recommending that the Commission defer a decision on the Petition to allow the voluntary standard process to continue until the APBR voluntary standard had been developed and evaluated by staff. On April 29, 2014, and April 28, 2015, the Commission voted to defer the Petition to allow staff to continue assisting in the development of the voluntary standard.

[9] The CPSC has a consumer product safety standard for children's portable bed rails, which incorporates ASTM F2085-19, and is codified at 16 CFR § 1224. (85 Fed. Reg. 10565).

[10] Staff's 2014 Briefing Package discussed the distinction between bed rails that are considered medical "devices" under the FDA's authority, and other bed rails that fall under CPSC's jurisdiction. Bed rails that are an accessory or an appurtenance to regulated hospital beds generally are considered by FDA to have a medical purpose and may be devices under FDA. Bed rails that are not medical devices generally would fall under the CPSC's jurisdiction, irrespective of where the bed is used (*e.g.*, nursing home, long-term care facility, or residence).

In August 2017, ASTM published an update to the voluntary standard, ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. From 2018 through 2019, staff collected and tested over 50 percent of the available APBR products on the market to the requirements of ASTM F3186 – 17. Staff provided a Petition update briefing package to the Commission on July 15, 2020, with staff's assessment of ASTM F3186 – 17 using the factors the Commission considers when deciding whether to grant or deny a petition.[11]

In the 2020 update, staff assessed whether the ASTM F3186 – 17 standard would likely eliminate or adequately reduce the risk of injury related to APBRs and whether there would likely be substantial compliance with the standard. Staff determined that the requirements of the voluntary standard would adequately address the associated hazards only with modifications described by staff, and staff did not find that APBRs on the market substantially complied with the voluntary standard. However, staff also noted that since many of the products tested did not denote their manufacturing dates, it was possible that some of the products tested could have been manufactured before the publication of the voluntary standard. Therefore, staff recommended an additional round of testing to support their assessment of whether substantial compliance to the voluntary standard would be likely in the future, as framed by the CPSA.[12] To encourage increased industry compliance during this timeframe, staff continued market outreach efforts, including a 2020 CPSC Office of Compliance and Field Operations (Compliance) letter to industry urging compliance with ASTM F3186 – 17 to reduce the risks of entrapment and strangulation associated with APBR products.[13]

Staff conducted a second round of APBR market compliance testing in 2021, which included every new APBR model that staff could identify as having entered the market since the previous review, and a random sample of models still available on the market. Staff's March 9, 2022 petition briefing package provided updates on the injury and market data previously reported to identify changes since the last review in 2020.[14] Despite the additional outreach and time allowed for manufacturers to adopt the voluntary standard, staff did not find any APBRs that wholly complied with the voluntary standard. Staff concluded that substantial compliance with the voluntary standard is not likely and recommended that the Commission grant the Petition.

On March 15, 2022, the Commission unanimously voted (4-0) to grant the Petition and directed staff to draft a notice of proposed rulemaking (NPR) briefing package.

---

[11] Staff Briefing Package, *Update on Petition CP 13-1, Petition Requesting a Ban or Standard on Adult Portable Bed Rails,* July 15, 2020. Retrieved from: https://www.cpsc.gov/s3fs-public/Update%20on%20Peititon%20CP%2013-1%20-%20Requesting%20a%20Ban%20or%20Mandatory%20Standard%20on%20Adult%20Portable%20Bed%20Rails.pdf?kiDixW5Z7x9xcOqjxSeS3QpvspdfQMBY

[12] 15 U.S.C. § 2056(b), 2058(f)(3)(D).

[13] Letter to Manufacturers, Importers, Distributors, and Retailers of Adult Portable Bed Rails and Related Products from Robert S. Kaye, Director, Office of Compliance and Field Operations, https://www.cpsc.gov/s3fs-public/APBR-Compliance-Letter-to-Industry-June22202001.pdf.

[14] Staff Briefing Package, *Petition CP 13-1, Petition Requesting a Ban or Standard on Adult Portable Bed Rails*, March 09, 2022. Retrieved from: https://www.cpsc.gov/s3fs-public/Petition-Requesting-a-Ban-or-Standard-on-Adult-Portable-Bed-Rails-Petition-CP-13-1.pdf

Notice of Proposed Rulemaking for Adult Portable Bed Rails

On September 21, 2022, staff submitted a draft NPR briefing package to the Commission. Pursuant to section 9 of the CPSA, the draft NPR briefing package included updates to staff's previously reported technical data, proposed language to incorporate by reference ASTM F3186 – 17 with specified modifications, a preliminary regulatory analysis for APBRs, and staff's initial regulatory flexibility analysis under the Regulatory Flexibility Act.

On October 12, 2022, the Commission voted unanimously (4-0) to approve publication of the proposed rule with specified changes.[15] The NPR was published in the *Federal Register* on November 9, 2022, 87 Fed. Reg. 67,586. The NPR solicited public comment on several topics related to APBRs, including whether the proposed adoption of the modified ASTM standard adequately addresses the hazard and whether a ban on the product is warranted as requested in the Petition. The 60-day public comment period closed on January 9, 2023. CPSC received seven written comments and no requests for oral comments in response to the NPR.

Once the comment period ended, staff developed a draft FR briefing package including staff's responses to the comments received, and any revised proposed language to include any recommended modifications to the FR.

Incident Data & Hazard Analysis

In support of the draft FR, staff refer to the Hazard Analysis Division of the Directorate for Epidemiology's (EPHA) summary of the data on deaths and injuries involving APBRs.[16] Along with the Directorate for Health Sciences (HS) and the Human Factors Division of the Directorate for Engineering Sciences' (ESHF) review of these data and the reported incidents which identified the affected population and the hazard patterns associated with APBRs.[17,18] Staff concludes that the most common hazard pattern is entrapment, accounting for 90 percent of fatalities, and that the majority of victims are elderly and/or suffering from an underlying medical condition.

[15] Record of Commission Action, Commission Vote October 12, 2022. Retrieved from: https://www.cpsc.gov/s3fs-public/RCA-Proposed-Rule-Safety-Standard-for-Adult-Portable-Bed-Rails.pdf?VersionId=1BpnfS2qveiIIuUNYe17hbVmxah.zFLc

[16] Staff Draft NPR, Tab A, Zhang, C. Memorandum by The Directorate for Epidemiology, Division of Hazard Analysis, *Adult Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries*, 2022.

[17] Staff Draft NPR, Tab B, Wanna-Nakamura, S. Memorandum by The Directorate for Health Sciences, Division of Pharmacology and Physiology Assessment, *Health Sciences Assessment for the Notice of Proposed Rulemaking for Adult Portable Bed Rails*, 2022.

[18] Staff Draft NPR, Tab C, Foster, Z. Memorandum by The Directorate for Engineering Sciences, Division of Human Factors, *Human Factors Engineering Analysis for the Notice of Proposed Rulemaking for Adult Portable Bed Rails*, 2022.

Incident Data

EPHA staff collected APBR-related incident data from two sources:

- CPSC's Consumer Product Safety Risk Management System (CPSRMS)[19]

  Data included reports from January 1, 2003, through December 31, 2021. Data collection is ongoing in CPSRMS, and reporting was considered incomplete for the latest 3 years.

- The National Electronic Injury Surveillance System (NEISS)[20]

  NEISS-based injury estimates are from January 1, 2003, to December 31, 2021; finalized NEISS data and estimates for 2022 were not available at the time of this report.

CPSRMS Incident Data Summary

Between January 2003 and April 2022, CPSC received 332 incident reports related to APBRs, with reported incidents occurring between January 2003 and December 2021. Of the 332 incidents, there were 310 deaths and 22 nonfatal incidents. Most of the reports were death certificates and medical examiner/coroner reports. The remaining reports were obtained through various sources, such as newspapers, consumer reports, and retailers/manufacturers. Staff organized the data by age, gender, location, and underlying medical condition. The data presented below considers only APBRs identified as under CPSC's jurisdiction and excludes those considered under FDA authority (i.e., bed rails that meet the definition of a medical device) based on the available facts.

Victims' ages ranged from 14 to 103 years old. At least 75 percent of the incident victims were age 70 or older, and around 80 percent of the reported fatalities involved victims ages 70 or older. Table 1 below presents the distribution of these APBR incidents by age.

[19] The most recent search of the CPSC databases for APBR incidents was conducted on April 15, 2022. This search was an update to a previous search that covered 2003 to September 2021 for CPSRMS, and 2003 to 2020 for NEISS. The product code searched was 4075, which encompasses all bed rail products. All cases where the primary victim was under 13 years of age were excluded from the analysis. Data from CPSRMS was reviewed to remove incidents that involved bed rail products that may be classified as medical devices under FDA jurisdiction.

[20] It should be noted that in the vast majority of NEISS cases, there was insufficient information available in the case narrative to determine whether the bed rail product involved was specifically an adult portable bed rail, or just a regular adult bed rail; only one case narrative specifies the product involved as an adult portable bed rail. Hence, the estimates presented in Table 5 (which provides an overview of the estimated number of adult bed rail-related injuries per year) may be overestimates. An estimated injury rate per 100,000 population has also been calculated, based on estimates of population ages 13 and older provided by the U.S. Census Bureau.

Table 1: Distribution of Reported APBR-Related Incidents by Age

Age Group (Years)	Fatalities	Nonfatalities	Total
13–29	7	0	7
30–59	30	0	30
60–69	22	0	22
70–79	47	2	49
80–89	124	2	126
90 or older	75	1	76
Unknown/Unspecified	5	17	22
Total	**310**	**22**	**332**

Source: CPSRMS (2003-2021).

Table 2 below details the distribution of these APBR-related incidents by gender. Approximately 70 percent of victims were female.

Table 2: Distribution of Reported APBR-Related Incidents by Gender

Gender	Fatalities	Nonfatalities	Total
Male	88	7	95
Female	221	8	229
Unknown/Unspecified	1	7	8
Total	**310**	**22**	**332**

Source: CPSRMS (2003-2021).

Approximately 50 percent of all APBR-related incidents and fatalities occurred at home. Other commonly reported locations include nursing homes, assisted living facilities, and residential institutions. Table 3 below shows the frequency of each location reported.

Table 3: Distribution of Reported APBR-Related Incidents by Location

Location	Fatalities	Nonfatalities	Total
Home	158	6	164
Nursing Home	50	0	50
Assisted Living Facility	40	2	42
Residential Institution	14	0	14
Other[21]	23	0	23
Unknown/Not Reported	25	14	39
Total	**310**	**22**	**332**

Source: CPSRMS (2003-2021).

Most reports (58 percent) indicated that the victim suffered from at least one underlying medical condition. Almost 34 percent were reported to have more than one medical condition. Table 4 below summarizes the most frequently reported medical conditions.

[21] Includes care home/center, foster home, group home, retirement center, adult family home and hospice.

Table 4: Distribution of Reported APBR-Related Incidents by Medical Condition[22,23]

Condition	Fatalities	Nonfatalities	Total
Cardiovascular disease	87	0	87
Alzheimer's/Dementia/Mental	73	0	73
Mobility/Paralysis/Stroke	20	0	20
Parkinson's disease	17	1	18
Pulmonary disease	11	0	11
Cancer	7	0	7
Cerebral palsy	6	0	6
Multiple sclerosis	5	0	5
Other[24]	21	0	21
Unknown/Not Reported	123	21	144

Source: CPSRMS (2003-2021).

NEISS Incident Data Summary

Between January 2003 and December 2021, there were an estimated 79,500 APBR-related injuries treated in hospital emergency departments across the United States. Table 5 below reports this data by year.

Table 5: NEISS Estimates for Injuries Related to Adult Bed Rails[25]

Year	Estimate[26]	Sample Size	Injury Rate[27]
2003	4,500	98	1.88
2004	3,400	82	1.39
2005	3,900	94	1.61
2006	3,400	72	1.38
2007	4,300	98	1.73
2008	4,200	102	1.67
2009	3,600	98	1.42
2010	4,000	100	1.56

[22] Table 4 sums to more than 332 due to multiple conditions reported.

[23] Per a review of the data used the NPR staff have corrected two counts that were previously reported. Staff have corrected the number of fatalities where pulmonary disease was reported as an underlying condition of the victim from 10 to 11, and staff has corrected the number of Other underlying medical conditions from 20 to 21.

[24] Other significant conditions included tracheotomy and G-tube, severe burn, post-surgery, fracture, seizure, Lesch–Nyhan syndrome, amyotrophic lateral sclerosis, multiple drug ingestion, renal disease, agitation, diabetes, sepsis, leukemia, severe disabilities, advanced age, and general weakness.

[25] Estimates rounded to nearest 100; rows may not add to total due to rounding.

[26] According to the NEISS publication criteria, an estimate must be 1,200 or greater; the sample size must be 20 or greater; and the coefficient of variation must be 33 percent or smaller. All yearly estimates meet these criteria, and thus, are reportable.

[27] Obtained by dividing NEISS estimates by U.S. Census Bureau population estimate for the respective year (for ages 13+). Rates shown as per 100,000 population. Latest data can be found here: National Population by Characteristics: 2020-2021 (census.gov)

2011	3,700	95	1.44
2012	3,100	81	1.20
2013	4,700	127	1.79
2014	4,400	108	1.66
2015	4,600	112	1.73
2016	3,700	91	1.36
2017	4,900	128	1.81
2018	4,300	104	1.55
2019	4,500	112	1.63
2020	5,100	113	1.82
2021	5,100	131	1.83
Total	**79,500**	**1,946**	

Source: NEISS (2003-2021).

Hazard Analysis

Staff reviewed the 332 CPSRMS APBR-related incident reports within CPSC's jurisdiction to identify all relevant hazard patterns. Table 6 below reports these incidents by type.

Table 6: CPSRMS APBR-Related Incident Reports by Hazard Type

Hazard Type	Fatalities	Nonfatalities	Total
Rail Entrapment	284	2	286
Falls	23	2	25
Structural Integrity	0	11	11
Miscellaneous	3	7	10

Rail Entrapments

The most common hazard pattern among all reported incidents is rail entrapment, accounting for more than 90 percent (284 of 310) of the fatal incidents. Rail entrapments include incidents in which the victim was caught, stuck, wedged, or trapped between the bed rail and the mattress or bed, between bed rail bars, or otherwise entrapped in or against the APBR. Based on the evidence provided, the head and neck were the most frequently involved body parts.

Staff determined that the most common reported cause of death related to APBRs is positional asphyxia, which is directly associated with rail entrapment. "Asphyxia" is defined as the failure of cells to thrive in the absence of oxygen, as a result of strangulation. Blood vessels in the neck that deliver oxygen to the brain are relatively unprotected and are susceptible to compression. Sustained limb compression, with or without airway blockage, can result in death, even when the body remains partially supported.

Falls

Staff identified falls as the second most common hazard pattern associated with APBRs, accounting for 25 incidents, including 23 fatalities. This hazard pattern includes incidents in

which the victim fell out of the bed, fell and hit the bed rail, fell after climbing over the bed rail, and other similar scenarios.

Structural Integrity

There were 11 incidents related to structural component problems (weld of bed rail broke and bed rail not sturdy). This category includes one laceration, one head bump, one bruise, two unspecified injuries, and six non-injury incidents.

Miscellaneous

Staff classified 10 incidents as miscellaneous problems (hanging on the bed rail after garment got caught, hand, arm, or leg laceration, pinched radial nerve against the bed rail, complaint about a misleading label, complaint about a bed rail that was noncompliant with the ASTM standard, and a claim against a bed rail manufacturer about an unspecified issue). This category includes three deaths, three lacerations, one pinched nerve, one unspecified injury, and two non-injury incidents that report related product concerns.

Staff's Analysis and Conclusion Regarding Incident & Hazard Data

Staff found that most incident victims in CPSRMS were members of two vulnerable populations.

- Elderly People
  - At least 75 percent of all injured victims were age 70 or older.
  - Around 80 percent of the reported fatalities involved victims ages 70 or older.
- Persons affected by medical conditions
  - 58 percent of victims suffered from at least one underlying medical condition.
  - Almost 34 percent of victims were reported to have more than one medical condition.

Staff also found that entrapment is the most prevalent hazard pattern associated with APBRs, accounting for more than 90 percent of all reported fatalities.

Staff's Assessment of Applicable Standards

Prior to the development of ASTM F3186 – 17, in accordance with the CPSA, staff conducted a search for safety standards applicable to APBRs. Staff identified a U.S. Food and Drug Administration (FDA) guidance document from 2006, *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment*, but this guidance document is not considered applicable to consumer products that are not designed for use on hospital beds or as medical devices. This guidance is relevant, however, to the identification of entrapment zones, as discussed below.

Staff conducted an additional search in 2022, but found no applicable standards for APBRs, other than ASTM F3186 – 17.[28]

Staff's Analysis of ASTM F3186 – 17

Pursuant to the CPSA, staff reviewed the requirements of ASTM F3186 – 17 and concluded that, even if implemented by manufacturers, the voluntary standard would not adequately address the identified hazard patterns related to APBRs. Staff concludes that modifications discussed in the NPR and in the Recommended Changes to the Final Rule Based on Comments section within this briefing package are necessary for the modified standard to adequately address the hazards. The sections below summarize the staff's analysis of the voluntary standard and its requirements.

Scope and Definition

ASTM F3186 – 17 establishes performance requirements for APBRs, related products, and APBR accessories, including requirements for resistance to entrapment, marking and labeling, instructional literature, and advertising.

Section 3.1.1 of ASTM F3186 – 17 defines an "adult portable bed rail" as:

> [A]n adjacent type bed rail, grab bar, assistive bar, transfer aid, cane or rail (henceforth identified as the product or products) intended by the manufacturer to be installed on, against, or adjacent to an adult bed. The product may vary in lengths (for example, full, half, or partial rails, grab bar or handle or transfer post or pole), and is intended by the manufacturer to aid the bed occupant in moving on the bed surface, in entering or exiting the bed, to minimize the possibility of falling out of bed, or for other similar purposes. This includes similar products that are likely to be used for these purposes even if this is not explicitly stated by the manufacturer. However, the standard does not address all products that might be so used, for example, a chair.

Section 3.1.2 of ASTM F3186 – 17 defines an "adjacent type bed rail" as:

> [A] portable bed rail or related product in which the guard portion (portion that an adult would contact when rolling toward the mattress edge) is essentially a vertical plane or pole that is positioned against the side of the mattress.

CPSC staff reviewed bed rails under CPSC's jurisdiction, including products that are installed or used along the side of a bed that are intended to reduce the risk of falling from the bed, assist the consumer in repositioning in the bed, or assist the consumer in transitioning into or out of the bed. Staff worked with the ASTM subcommittee to develop the definitions in the standard

[28] Staff's international search returned three potentially applicable standards for bed rail products in general, but after a more detailed review, the standards were similar to the FDA guidance document and mostly focused on products that were considered medical devices, which is outside of CPSC's jurisdiction.

based on the scope of the Petition and the types of APBRs that are not covered by CPSC's existing regulations for children's bed rails.[29]

General Requirements

ASTM F3186 – 17 includes general requirements in Section 5. Section 5.1 requires that there will be no hazardous sharp points or edges. Section 5.2 states that any exposed parts shall be smooth and free from rough edges. Prohibiting sharp points and requiring smooth edges on exposed parts improves safety by preventing lacerations or abrasions.

Section 5.3 requires that products covered by the standard that can be installed on a bed that articulates (*i.e.*, an adjustable bed) meet the performance requirements when the bed is in both flat and articulated positions. Testing APBRs on articulating beds is necessary because openings that could lead to entrapment when the bed is articulated may not exist when the bed is in the flat position.

Performance Requirements

In addition to the general requirements in section 5, ASTM F3186 – 17 includes several performance requirements intended to address the risk of injury associated with APBRs. These include requirements for assembly, structural integrity, retention system performance, and fall and entrapment prevention.

Misassembly and Misinstallation

Rail entrapment accounts for more than 90 percent of all fatal APBR incidents. Effectively addressing the entrapment hazard associated with APBRs depends upon, among other things, the product being designed so that consumers assemble and install the product properly. If an APBR appears functional, even though it is not fully assembled or properly installed, a consumer may use the product and unknowingly be exposed to entrapment hazards. ASTM F3186 – 17 includes performance requirements intended to increase the likelihood that the APBR will be assembled and installed properly. For example:[30]

- Section 6.1 requires products to include a retention system, which maintains the installed product in position without requiring readjustment of the components. This retention system must be permanently attached to the APBR once it has been assembled and must not be removable without the use of a tool.
- Section 6.2 includes structural integrity requirements that call for the product to extend a minimum height above the mattress, and that it shall not deform or cause hazardous conditions throughout testing.

[29] 16 C.F.R. § 1224 (85 Fed. Reg. 10,565). *Safety Standard for Portable Bed Rails*, Consumer Product Safety Commission. Retrieved from: https://www.govinfo.gov/link/cfr/16/1224?link-type=pdf&year=mostrecent

[30] Although Sections 6.3 and 6.4 for entrapment and openings, respectively, do not directly address misassembly and misinstallation, both include performance requirements that are applicable to products that may be misassembled or misinstalled.

- Section 6.5 requires that structural components and retention system components must not be capable of being misassembled, which the standard defines as the APBR being assembled in a way that appears functional but would not meet the retention system (Section 6.1), structural integrity (6.2), entrapment (6.3), or openings (6.4) requirements.

Staff concluded that the requirements in sections 6.1 and 6.5, requiring retention systems to be permanently attached to the APBR once it has been assembled and removable only with a tool, reduces the likelihood that consumers will misplace the retention system. It also increases the likelihood that consumers, including secondary users, will continue to use the retention system because it will always be present with the product. The structural integrity requirements ensure the product will be installed so that it is stable enough to support users and does not create hazards during use. The requirement that structural and retention system components not be capable of being misassembled reduces the risk of injury or death that could arise from the consumer omitting key parts of the APBR (*e.g.*, a center rail) during assembly, in ways that could result in entrapment or other hazards.

Falls

Falls were the second most common hazard pattern in the incident data, accounting for 25 incidents (8 percent). Staff found that most falls associated with APBRs involve the victim falling against or striking the APBR, but these incident reports usually have only limited details. Therefore, the APBRs might have played an incidental role in some of these cases. If the fall was triggered by the APBR becoming dislodged, or its position shifted, then these incidents would likely be addressed by the voluntary standard's structural integrity testing and the requirement of a permanently attached retention system to maintain the installed product in position.

A small number of fall-related incident reports, according to staff's review of incidents, involved the victim deliberately climbing over the APBR. Section 6.2 of ASTM F3186 – 17 includes a "structural integrity" requirement that calls for the installed APBR to extend at least 4 inches above the top of the thickest recommended mattress. The minimum height requirement for APBRs may address fall incidents by limiting the ability of consumers to climb over these products. However, this requirement may not prevent consumers from falling, such as in cases where a person climbs over an APBR.

Entrapment Testing

Staff identified entrapment as the most prevalent hazard pattern among the reported incidents. In accordance with the entrapment test methods specified in Section 8 of ASTM F3186 – 17, Section 6.3 requires products to be tested to assess the potential for entrapment in four different zones. These zones represent four of the seven sectors identified in the 2006 FDA guidance document, *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment* (FDA, 2006), as potential areas of entrapment in hospital bed systems. Staff's review of APBR entrapment incidents showed that almost all the entrapment-related fatalities occurred in the four zones covered by ASTM F3186 – 17 (zones 1 through 4 in the FDA guidance document). Zone 5, the area between two side rails on the same side of a bed, is not applicable because,

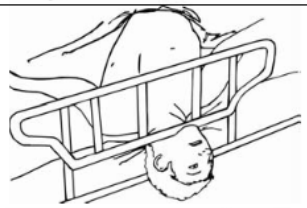
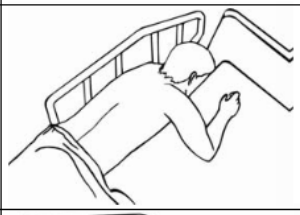
generally, only a single APBR is installed on a given side. Although CPSC staff is aware of an incident in which two separate APBRs were installed on the same side of a bed, currently, staff is not aware of any incidents identified as Zone 5 entrapments. Zone 6 is the area between the end of the rail and the side edge of the bed headboard or footboard. Although this location is relevant to APBRs, these products are installed by the consumer, so the potential for entrapment is dependent upon the consumer's placement of the APBR on the bed, which is addressed in the labeling and warning requirements. Zone 7 involves the space between the end of the mattress and the headboard or footboard and is therefore not applicable to APBRs. The FDA's guidance is based on recommendations from the Hospital Bed Safety Workgroup (HBSW), which was formed in 1999 to address reports of patient entrapment.[31,32] ASTM F3186 – 17 section 7.2 specifies use of the cone and cylinder tool described in the FDA guidance document as the probe used to test entrapment zones. The probe design is based on the anthropometric dimensions of key body parts, including the head, neck, and chest of at-risk adults.

Section 8.4 defines the four entrapment zones tests under ASTM F3186 – 17, which are: (1) within the product; (2) between rail support(s) and the bed mattress, when applicable, under the product; (3) between the product and the mattress; and (4) between the underside of the end of the product and the mattress. Section 8.4 requires entrapment testing to determine compliance with ASTM F3186 – 17 using the anthropometric "entrapment test probe," which is the cone and cylinder tool described in the 2006 FDA guidance document (Section 7.2). In addition, some entrapment zones require using a force gauge to test the force applied on the test probe (Section 7.3). Table 7 below, describes the four entrapment zones, with illustrations from the 2006 FDA guidance document of sample entrapments within each of these zones.

[31] The FDA guidance document is available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment. (FDA, 2016). Three of the zones identified in the FDA guidance (Zone 5, Zone 6, and Zone 7) were not applicable to APBRs, or could not be tested for entrapment under ASTM F3186 – 17, and therefore, they are excluded from the standard.

[32] The HBSW was formed by the FDA, in partnership with the U.S. Department of Veterans Affairs, Health Canada's Medical Devices Bureau, and representatives of national health care organizations and provider groups, patient advocacy groups, and medical bed and equipment manufacturers. The 2006 document includes a full list of HBSW participating organizations. The HBSW also worked in cooperation with the Joint Commission on Accreditation of Healthcare Organizations, the U.S. Centers for Medicare and Medicaid Services, and the CPSC to improve patient safety associated with the use of hospital beds.

Table 7: ASTM F3186 – 17 Entrapment Zones

Zone 1: Within the Product Entrapment in any open space within the perimeter of the APBR	
Zone 2: Between Rail Support(s) and the Bed Mattress, When Applicable, Under the Product Entrapment under the bottom edge of the APBR, between the rail supports or next to a single rail support, against the mattress	
Zone 3: Between the Product and the Mattress Entrapment in the space between the inside surface of the APBR and the side of the mattress	
Zone 4: Between the Underside of the End of the Product and the Mattress Entrapment under the lowermost portion of the end of the APBR, against the mattress	

Staff's review of the rail entrapment incidents, test requirements (section 6.3), and test methods (section 8.4) showed that most of the reported entrapment fatalities involved one of the four zones listed above. Specifically, staff could determine the entrapment location of 214 of the 284 fatal incidents, and all but six of these cases occurred in one of the four entrapment zones tested in ASTM F3186 – 17, as shown in Table 8 below. Based on this analysis, it is likely that most of the 70 incidents, for which there was insufficient information in the report to identify the location of the entrapment, also involved one of these four zones.

Table 8: Rail entrapment incident locations relative to zones tested in ASTM F3186 – 17

Rail Entrapment Location	Entrapment Testing Location	No. of Fatalities
Between APBR and mattress	Zones 2, 3, or 4	200
Within APBR itself	Zone 1	8
Against outside of APBR	None	5
Between APBR and headboard	None (Zone 6)	1
Unknown location	Unknown	70
Total		**284**

Staff's finding that rail entrapments predominantly occur in Zones 1 through 4 is consistent with the FDA's finding that these four zones accounted for about 80 percent of hospital bed rail entrapment events reported to the FDA. This finding was the basis for the FDA's recommended dimensional limits for these zones and the anthropometric test probe, which are used in the entrapment requirements of ASTM F3186 – 17.

Staff determined in the July 15, 2020 briefing package that the FDA entrapment test probe used in the voluntary standard could be reasonably used to identify entrapment hazards related to APBRs, based on the identified entrapment patterns and related anthropometric data. However, both staff and the Commission preliminarily determined that the performance requirements in the voluntary standard, including testing entrapment zones using the FDA entrapment test probe, would not adequately address the entrapment hazards posed by APBRs.

Labeling, Warning, and Instructional Literature Requirements

Section 9.1 of ASTM F3186 – 17 specifies that the labeling on the APBR and its retail packaging must be marked with the type and size of beds and mattresses, including the mattress thickness range, for which the APBR is intended. In addition, the labeling and retail packaging on the APBR must state the appropriate distance between an installed APBR and the headboard or footboard of the bed. ASTM F3186 – 17 requires labels in section 9.1, including labels that instruct the consumer on how to correctly install the APBR at the specified distance from the headboard or footboard to prevent entrapment. The hazard is addressed by requiring labeling on the APBR to state the appropriate distance between an installed APBR and the headboard or footboard of the bed. Sections 9.1 and 10 also specify that all on-product labels must be permanent.

Section 9.2 establishes requirements for warning statements that must appear on the APBR, retail packaging, instructions, and/or digital or print advertising. The warning statements must be easy to read and understand, and any other labels or written instructions provided along with the required statements cannot contradict or confuse the meaning of the required warnings or otherwise be misleading. These warnings address entrapment, strangulation, suffocation, and fall hazards associated with APBRs and provide general guidance to consumers on how to mitigate these hazards.

Section 11 specifies requirements for instructional literature that must accompany APBRs. The instructions provided must be easy to read and understand; include assembly, installation, maintenance, cleaning, operation, and adjustment instructions and warnings, where applicable; include drawings or diagrams to provide a better understanding of set up and operation of the product; include drawings that depict all the entrapment zones; and include all warning statements specified in Section 9.2, including warnings about product damage or misalignment.

Although staff concludes that relying on labeling, warning, and instructional requirements is less effective at reducing hazards than product designs that directly address known hazards, staff found that these requirements in the standard provide important supplementary safety measures for risks that may not be eliminated through the product design.

Staff's Assessment of ASTM F3186 – 17 Performance Requirements

Staff's NPR briefing package concluded that compliance with the voluntary standard would not address all known product hazard modes associated with APBRs without modifications for improved clarity and effectiveness. Although staff found that the standard does address the risk of injuries and fatalities associated with APBRs, staff has identified areas of the standard that must be improved upon in order to adequately protect consumers. Proposed improvements published in the NPR briefing package include corrections to the requirements for labels and warnings, and several corrections and clarifications for certain test procedures, such as entrapment and opening testing. These modifications are listed in the Modifications to ASTM F3186 – 17 Included in the NPR section of this briefing package.[33] Staff's analysis of incident data, included in the NPR briefing package, indicated that the identified hazard patterns continue to occur because manufacturers currently do not comply with the voluntary standard, as discussed in the section below. Staff has not identified any new patterns based on incidents since the NPR pertaining to the assessment of ASTM F3186 – 17 for this draft FR, and therefore staff's conclusion remains the same.

Staff's Assessment of Market Compliance to ASTM F3186 – 17

Staff conducted two rounds of APBR market compliance testing to ASTM F3186 – 17. The first round was in in 2018 and 2019, the second round was in 2021.[34] In both rounds of market compliance testing, none of the APBR products met all the requirements of ASTM F3186 – 17. All products failed at least one critical mechanical requirement, such as retention strap performance, structural integrity, or entrapment. As described in the sections above, an APBR that fails any one mechanical performance requirement could result in a fatal entrapment of a consumer or other known hazard. Finally, all products failed the labeling, warning, and instructional requirements of the standard. This section summarizes:

- Staff's 2018-2019 Market Compliance Testing
- Staff's market outreach activities following the results of the 2018 Market Compliance Testing, and;
- Staff's 2021 Market Compliance Testing.

2018-2019 APBR Market Compliance Testing

In 2018-2019, CPSC staff tested 35 randomly selected APBR models for compliance with ASTM F3186 – 17, which became effective in August 2017. All APBRs tested were purchased in 2018. Staff of CPSC's Directorate for Laboratory Sciences Division of Mechanical Engineering (LSM) tested the products to determine if they conform to the general and

[33] These modifications are also explained in further detail in Tab F of staff's NPR briefing package.
Staff Draft NPR, Tab F, Howie,A. Memorandum by the Directorate for Laboratory Sciences, Division of Mechanical Engineering, *Proposed Changes to ASTM F3186 – 17*, 2022

[34] Staff Draft NPR, Tab D, Ota, G. Memorandum by The Directorate for Laboratory Sciences, Division of Mechanical Engineering, *Mechanical Engineering Analysis for the Notice of Proposed Rulemaking for Adult Portable Bed Rails*, 2022

performance requirements of the voluntary standard, ASTM F3186 – 17. ESHF staff tested for conformance with the labeling, warning, and instructional literature requirements. Staff found that none of the 35 sampled products conformed to the voluntary standard's requirements. Staff concluded that market compliance with the standard was likely low when staff purchased the samples in 2018. However, due to the lack of proper labeling, staff could not confirm that all products were manufactured after the standard's effective date. As shown in Table 9 below, compliance varied by section of the standard. Overall, 33 APBR models did not meet the entrapment performance requirements, and none of the 35 models met the labeling, warnings, or instructional literature requirements.

Table 9: Summary of 2018-2019 APBR Market Compliance Testing to ASTM F3186 – 17

Section		Title	# of Failed Samples (of 35 Total Samples Tested)	Failure Rate
General Requirements	5.1	Hazardous Points/Edges	0	0%
	5.2	Jagged Surfaces	0	0%
	5.3	Articulated Beds	0	0%
Performance Requirements	6.1	Retention Systems	28	80%
	6.2	Structural Integrity	15	43%
	6.3	Entrapment	33	94%
	6.4	Openings	0	0%
	6.5	Misassembled Products	8	23%
Labels and Warnings Requirements	9.1	Labeling	35	100%
	9.2	Warning Statements	35	100%
Instructional Literature	11	Instructional Literature	35	100%

The entrapment hazard pattern was the most prevalent hazard pattern among the reported incidents identified in the 2020 briefing package, accounting for 226 of the 260 reported incidents. Of the 35 APBR models staff tested, 33 failed at least one of the entrapment requirements for the four zones in and around the APBR. In other words, 94 percent of samples had at least one major zone where a body part could become entrapped. Furthermore, many samples failed the entrapment requirements for multiple zones: 14 failed the Zone 1 entrapment requirement; 27 failed Zone 2; 11 failed Zone 3; and 6 failed Zone 4.

Staff's testing also revealed high failure rates for several other sections of the voluntary standard, including the retention system requirements (28 of 35 samples), and the structural integrity requirements (15 of 35 samples). These types of failures indicate that the product may not stay rigidly in place after installation and will not adequately support the consumer during

normal use conditions, such as leaning against the product. Failure to meet these requirements significantly increases the likelihood of entrapment and fall hazards.

Retention system failures occurred when components were not permanently attached to the product, the retention strap permanently deflected or detached during the free end pull test, or the retention system did not restrain the product during entrapment testing.[35]

Structural integrity failures occurred when the APBR did not extend at least 4 inches over the top of the thickest recommended mattress, or when fasteners loosened or detached during testing, causing the product to change dimensions.[36]

All 35 models failed the labeling, warning, and instructional literature requirements. None of the 35 models fully met the following labeling requirements: Section 9.1 for retail packaging and product labels; Section 9.2, which specifies that warning statements must appear on the product, its retail package, and its instructions; and Section 11's requirement to include instructional literature with required warning statements. None of the samples adequately instructed consumers on how to safely install the APBRs; nor did the samples adequately inform consumers of the known hazards related to APBRs. Detailed testing results are provided in Appendix A of staff's NPR briefing package.[37]

Market Outreach (2020-2021)

To promote market awareness of the voluntary standard and associated hazards, staff conducted outreach through CPSC's Office of Compliance and Field Operations (Compliance). In June 2020, Compliance staff sent a letter to 19 known APBR manufacturers, urging them to ensure that their APBRs comply with ASTM F3186 – 17.[38] The letter also reminded firms of the dangers of entrapment and strangulation hazards, and it warned that CPSC "may regard [non-compliant] products as having a defect which could present a substantial product hazard under section 15(a) of the Consumer Product Safety Act."

In addition, since completing the 2018 market compliance testing, staff continues to actively engage with the ASTM F15.70 subcommittee. The subcommittee membership includes representatives from manufacturers, third party test facilities, consumer advocates, and government agencies. Staff has presented and explained each round of staff's testing results to

[35] The free end pull test requires the application of a 50 lbf (222.5 N) pull force on the free end of the retention system. The retention system must maintain the product in a position to perform to the other test methods in the standard, including entrapment tests, without requiring readjustment.

[36] Most products did not include a maximum recommended mattress height. In those cases, staff considered any mattress readily available to the public. In addition, the voluntary standard requires all products to be tested fully assembled in accordance with the manufacturer's instructions. However, several APBR manufacturers did not specify or instruct the user how to set the product's adjustable features. In the absence of direction from the manufacturer, CPSC staff adjusted the product's height to the height least likely to pass.

[37] Due to the nature of the test, 9.1.2 was considered a mechanical test in the 2018-2019 data set. There were no products that met the remaining requirements of Section 9.1, Section 9.2, and Section 11

[38] Letter to Manufacturers, Importers, Distributors, and Retailers of Adult Portable Bed Rails and Related Products from Robert S. Kaye, Director, Office of Compliance and Field Operations, https://www.cpsc.gov/s3fs-public/APBR-Compliance-Letter-to-Industry-June22202001.pdf.

the subcommittee members, provided the subcommittee with Compliance's letter to industry for all its members to review and disseminate, supplied updated incident data for the subcommittee's review, informed the subcommittee of staff briefing packages sent to the Commission and related Commission actions, and has participated as technical experts with all subcommittee task groups.

2021 APBR Market Compliance Testing

In 2021, staff conducted a second round of product testing for compliance to ASTM F3186 – 17 to determine if the additional time and outreach since 2018 was effective in getting manufacturers to increase the overall level of compliance to the standard. A total of 17 APBR products were selected and procured for testing: these included all eight APBR models that staff identified as new to the market since the 2018 analysis, and nine additional, randomly selected models from the rest of the available market. The nine randomly selected models were products previously identified in the 2018 analysis and were included to account for any undisclosed changes to the models that may have improved their compliance with the voluntary standard.

The 2021 testing, like the 2018 testing, assessed overall compliance to the voluntary standard, with a focus on certain sections, including Retention Systems, Structural Integrity, Entrapment, Openings, Misassembled Products, Warning Statements, and Instructional Literature. All samples were tested until at least one of the performance requirements for Retention Systems, Structural Integrity, or Entrapment were not met. All 17 samples failed at least one of the performance requirements in the voluntary standard. Detailed testing results are provided in Appendix B of staff's NPR briefing package.[39]

Additionally, none of the 17 models tested met the labeling, warnings, and instructional literature requirements in the voluntary standard. As shown in Table 10 below, the failure modes of this analysis are similar to the results of the 2018 analysis, indicating little-to-no change in compliance with the voluntary standard in the market over this time.

[39] Because testing of a sample was subject to stop at any critical failure, full testing to the standard was not completed in 2021, and the data collected may not account for all the potential failure modes per product.

Table 10: ASTM F3186 – 17, 2021 APBR Market Compliance Testing Result Summary

Section		Title	# of Failed Samples	# of Samples Tested
General Requirements	5.1	Hazardous Points/Edges	0	17
	5.2	Jagged Surfaces	0	17
	5.3	Articulated Beds	-	0
Performance Requirements	6.1	Retention Systems	13	17
	6.2	Structural Integrity	7	7
	6.3	Entrapment	14	16
	6.4	Openings	-	0
	6.5	Misassembled Products	1	1
Labels and Warnings Requirements	9.1	Labeling	17	17
	9.2	Warning Statements	17	17
Instructional Literature	11	Instructional Literature	17	17

Section 15 Compliance Actions 2021 – 2022

From 2021 to 2023, CPSC Compliance staff issued two unilateral notices and announced six voluntary recalls of APBRs that did not comply with ASTM F3186 – 17 requirements.[40,41]

In April 2021, CPSC Compliance staff issued a unilateral warning to consumers to stop using three models of APBRs manufactured by Bed Handles, Inc., because the products pose an entrapment hazard.[42] Bed Handles, Inc., manufactured approximately 193,000 units of the APBRs, and CPSC is aware of four entrapment deaths associated with the product.

In December 2021, CPSC announced voluntary recalls of APBRs manufactured by three firms, due to the entrapment hazard and risk of death by asphyxia posed by their products:

- Drive DeVilbiss Healthcare (496,100 units, 2 deaths);[43]
- Compass Health Brands (104,900 units, 3 deaths); and[44]

[40] Staff Draft NPR, Tab E, O'Donnell, C. Memorandum by The Office of Compliance and Field Operations, Division of Enforcement and Litigation, *Adult Portable Bed Rails Summary of Compliance Actions since June 2020*, 2022.

[41] Staff Draft FR, Tab A, O'Donnell, C. Memorandum by The Office of Compliance and Field Operations, Division of Enforcement and Litigation, *Adult Portable Bed Rails Summary of Compliance Actions since June 2020*, 2023

[42] PR #21-122, https://www.cpsc.gov/Newsroom/News-Releases/2021/CPSC-Warns-Consumers-to-Stop-Use-of-Three-Models-of-Adult-Portable-Bed-Rails-Manufactured-by-Bed-Handles-Inc-Due-to-Entrapment-Asphyxia-Hazard.

[43] PR #22-025, https://www.cpsc.gov/Recalls/2022/Drive-DeVilbiss-Healthcare-Recalls-Adult-Portable-Bed-Rails-After-Two-Deaths-Entrapment-and-Asphyxiation-Hazards.

[44] PR #22-040, https://www.cpsc.gov/Recalls/2022/Compass-Health-Brands-Recalls-Carex-Adult-Portable-Bed-Rails-After-Three-Deaths-Entrapment-and-Asphyxiation-Hazards.

- Essential Medical Supply, Inc. (272,000 units, 1 death).[45]

In June 2022, CPSC unilaterally warned consumers to stop using 10 models of APBRs manufactured and sold by Mobility Transfer Systems, Inc., from 1992 to 2021, and by Metal Tubing USA, Inc., in 2021 and 2022. Three entrapment deaths involving one model have occurred.[46] Mobility Transfer Systems, Inc., is no longer in business, and neither firm had agreed to conduct a recall. Approximately 285,000 units were manufactured.

In December 2022, CPSC announced the voluntary recall of two APBR models manufactured by Nova Ortho-Med, Inc. (Nova), due to their entrapment hazard and risk of asphyxia.[47] Nova distributed approximately 20,000 recalled APBRs.

In February 2023, CPSC and Platinum Health, LLC (Platinum), recalled three models of LumaRail brand APBRs.[48] Platinum distributed approximately 53,000 units of APBRs. CPSC is aware of one entrapment death associated with them.

In March 2023, CPSC announced the voluntary recall of two models of Vaunn Medical Bed Assist Rail APBRs that pose an entrapment hazard and risk of asphyxia.[49] Einstein Associates, LLC, sold approximately 102,000 units.

CPSC Compliance and Field Operations staff continues to investigate reports of entrapments involving APBRs on an ongoing basis.

Staff's Conclusion Regarding APBR Market Compliance Testing

Staff's review of the marketing testing conducted indicates that there is little-to-no market compliance with the ASTM voluntary standard. Despite the time allowed for manufacturers to adopt the voluntary standard since 2017, and staff's outreach efforts since publication of ASTM F3186 – 17, fatal entrapment incidents continue to rise. Staff concludes that substantial compliance to ASTM F3186 – 17, the voluntary APBR safety standard, is not likely, and that a mandatory regulation is necessary to prevent future deaths and injuries caused by the identified hazard patterns for APBRs.

Modifications to ASTM F3186 – 17 Included in the NPR

The following section includes the language for the additional requirements and changes the Commission proposed in § 1270.2(b) of the NPR that supplement the requirements in ASTM

[45] PR #22-039, https://www.cpsc.gov/Recalls/2022/Essential-Medical-Supply-Recalls-Adult-Portable-Bed-Rails-Due-to-Entrapment-and-Asphyxia-Hazard-One-Death-Reported.

[46] PR #22-148, https://www.cpsc.gov/Newsroom/News-Releases/2022/CPSC-Urges-Consumers-to-Immediately-Stop-Use-of-Mobility-Transfer-Systems-Adult-Portable-Bed-Rails-Due-to-Entrapment-and-Asphyxia-Hazard-Three-Deaths-Reported.

[47] PR #23-081, https://www.cpsc.gov/Recalls/2023/Nova-Medical-Products-Recalls-Adult-Bed-Rails-Due-to-Serious-Entrapment-and-Asphyxia-Hazards.

[48] PR #23-136, https://www.cpsc.gov/Recalls/2023/Platinum-Health-Recalls-LumaRail-Adult-Portable-Bed-Rails-Due-to-Serious-Entrapment-and-Asphyxia-Hazard-One-Death-Reported.

[49] PR #23-151, https://www.cpsc.gov/Recalls/2023/BeyondMedShop-Recalls-Vaunn-Medical-Adult-Bed-Rails-Due-to-Serious-Entrapment-and-Asphyxia-Hazards.

F3186 – 17. The language includes all the proposed changes to ASTM F3186 – 17 that CPSC published in the *Federal Register* for Public Comment, along with staff's rationale for each additional requirement or change. For additional information on these proposed changes and rationales refer to Tab F of staff's NPR briefing package.

Proposed Requirements in § 1270.2(b) from the NPR

Comply with the ASTM F3186-17 standard with the following changes:

(1) In addition to complying with section 3.1.7 of ASTM F3186-17, each adult portable bed rail must comply with the following:

(i) *3.1.8 Initial assembly.* The first assembly of the product components after purchase, and prior to installing on the bed.

(ii) *3.1.9 Initial installation.* The first installation of the product onto a bed or mattress.

Rationale: These definitions are intended to differentiate between "assembly" and "installation" so manufacturers can ensure products meet the requirements of sections 6.1.3 and 9.2.7 (see below).

(iii) *3.1.10 Installation component.* Component(s) of the bed rail that is/are specifically designed to attach the bed and typically located under the mattress when in the manufacturer's recommended use position.

Rationale: This term was previously used throughout the standard but was not defined. This definition is required to establish the location of warning from section 9.2.7 (see below). This definition is adopted from the Children's Portable Bed Rail standard (16 CFR § 1224).

(2) Instead of complying with section 6.1.3 of ASTM F3186-17, comply with the following:

(i) Under section 6.1.3, permanently attached retention system components shall not be able to be removed without the use of a tool after initial assembly.

Rationale: Making the retention system permanent during product assembly ensures that retention system integrity is maintained, even if the product is reinstalled after initial assembly. Retention systems are a critical component for reducing known product hazards. Removable retention systems are known to lead to entrapment and strangulation hazards. The retention system should remain attached to the product and should not be compromised after initial assembly and between uninstallation, and reinstallation of the product.

(3) In addition to complying with section 6.2.1 of ASTM F3186-17, comply with the following:

(i) Under section 6.2.1.1, if the manufacturer does not recommend a specific applicable range of mattress heights or thicknesses, the test personnel shall choose a mattress that provides the most severe condition per test requirement. If the product has adjustable settings, and the manufacturer does not recommend orienting or adjusting features on the product in a specific manner,

the testers shall adjust the product to the most severe condition per test requirement.

Rationale: Defining a range of recommended mattress thicknesses provides consumers with necessary information for safe use of the product. If no mattress thickness is recommended, consumers may incorrectly assume safe use with any mattress thickness. Similarly, products may come with many types of adjustable settings. If appropriate setting recommendations are not provided, consumers may incorrectly assume all settings are safe. This requirement does not supersede misassembly requirements in section 6.5 but is proposed to be applied in addition to those requirements.

(4) Instead of complying with section 6.3.3 of ASTM F3186-17, comply with the following:

(i) *6.3.3. Zone 3.* When tested in accordance with section 8.4.5, the horizontal centerline on the face of the 4.7 in (120 mm) end of the test probe (see 7.2) shall be above the highest point of the uncompressed mattress.

Rationale: The Zone 3 entrapment performance requirement in section 6.3.3 is redundant due to the failure criteria described in the associated test method, section 8.4.5.4. The failure criteria described in the test method is the intended requirement, which would also be more consistent with the FDA guidance document referenced in the standard, and is the interpretation in favor of safety. In addition, the Figures are proposed to assist testers in visualizing the test criteria.[50]

(5) Instead of complying with section 6.4.1 of ASTM F3186-17, comply with the following:

(i) Under section 6.4.1, holes or slots that extend entirely through a wall section of any rigid material less than 0.375 in (9.53 mm) thick and admit a 0.210 in (5.33 mm) diameter rod shall also admit a 0.375 in (9.53 mm) diameter rod. Holes or slots that are between 0.210 in (5.33 mm) and 0.375 in (9.53 mm) and have a wall thickness less than 0.375 in (9.53 mm) but are limited in depth to 0.375 in (9.53 mm) maximum by another rigid surface shall be permissible (see Opening Example in Figure 2 of ASTM F3186-17).

Rationale: The measurement references in 6.4.1 were not consistent or accurate with itself or the referenced Figure 2. The proposed changes to this section fixes those issues and harmonizes the requirements with other established ASTM standards that have similar requirements, including F2085 (Children's Portable Bed Rails).

(6) Instead of complying with section 6.5.1 of ASTM F3186-17, comply with the following:

(i) Under section 6.5.1, any structural components and retention system components of a product covered by this specification that require consumer assembly or adjustment, or components that may be removed by the consumer

[50] The proposed Figure 4 would not replace the existing Figure 4 in the standard. The existing Figure 4 will be renumbered to Figure 5, and all citations will be adjusted accordingly.

without the use of a tool, shall not be able to be misassembled when evaluated to 6.5.2.

Rationale: Editorial change to clarify that disassembly with the use of a tool is not considered to be "misassembly" under section 6.5.

(7) Instead of complying with section 6.5.2 of ASTM F3186-17, comply with the following:

(i) *6.5.2 Determining misassembled product.* A product covered by this specification shall be considered misassembled if it appears to be functional under any condition and it does not meet the requirements of sections 6.1-6.4.

Rationale: Editorial change, misspelling

(8) In addition to complying with section 7.1 of ASTM F3186-17, comply with the following:

(i) Under section 7.1.3, mattress thickness ranges used for testing may be up to 1.5 in (38 mm) larger or smaller than the range specified by the manufacturer. If the manufacturer does not recommend a particular range of mattress heights, the testers shall choose a mattress that provides the most severe condition per test requirement.

Rationale: Consumers are not expected to be able to consistently measure mattress thickness, nor are they expected to purchase a new mattress for proper compatibility. Additionally, consumers are likely to follow nominal descriptors of their mattresses which may vary from actual specifications. This additional range will increase safety by accounting for foreseeable reasonable differences between nominal and actual mattress thicknesses.

Note 1 to Paragraph (b)(8)(i): The technology and consumer preferences for bedding are highly variable and continuously changing. Therefore, they cannot be reasonably accounted for within this standard. Test facilities and personnel should consider current bedding trends and all types of mattresses that may foreseeably be used with the product when making a test mattress selection.

Rationale: Mattress type is a known variable for testing that is continuously changing. Manufacturers and testers should be aware of the types of mattresses consumers may be using with these products and test accordingly. Adopting this note would constitute "Note 2".

(9) In addition to complying with section 7.2 of ASTM F3186-17, comply with the following:

(i) *7.2. Entrapment test probe.* The test probe shall be as described in the FDA Guidance Document, "*Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment,* " which can be found at: *www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment.* The test probe can be independently manufactured per the dimensional constraints in the guidance document or purchased from Bionix, 5154 Enterprise Blvd., Toledo, OH

43612, 800-551-7096, *www.bionix.com.* Videos illustrating use of the test probe are available at: *www.youtube.com/c/BionixLLC/search.*

Rationale: Editorial change, the previous hyperlink and business contact information was out of date. The updated company information is as follows: Bionix, 5154 Enterprise Blvd, Toledo, OH 43612, 800-551-7096, https://bionix.com. Videos illustrating use of the test probe are available at: https://www.youtube.com/c/BionixLLC/search?query=Bed%20Rail.

(10) Instead of complying with Note 1 in section 8.4 of ASTM F3186-17, comply with the following:

Note 1 to Paragraph (b)(10)(i): The tests described in this section are similar to those described in the referenced FDA Guidance Document.

Rationale: Editorial change. Although the FDA guidance document is the source of the entrapment test methodologies, there are several differences in this standard in favor of safety and to make the tests more applicable to the consumer product versions of hospital bedrails. Note number was changed to 3 to align with other proposed changes.

(11) Instead of complying with section 8.4.3.4 of ASTM F3186-17, comply with the following:

(i) Under section 8.4.3.4, if the test probe does not pull through, freely attach the force gauge and exert a 22.5 lbf (100 N) pulling force along the axis of the cone, perpendicular to the 2.4 in (60 mm) cylindrical end of the entrapment test tool. If the 4.7 in (120 mm) end of the cone does not enter any of the openings, this space passes the test. If the 4.7 in (120 mm) end of the test probe cone does enter any of the openings, this space fails the test.

Rationale: The intent of this test is not to test the probe in both directions after being placed. It is to determine if both the 2.4 in and 4.7 in portions of the test probe cone can enter or pass through any Zone 1 opening under the required force. This would mean that a body part can be entrapped, and a hazard is present. Furthermore, applying the force perpendicular to the opening may have multiple interpretations; it also may not always emulate the known hazard of head or limb entrapment. Applying the pull force perpendicular to the 2.4 in cylindrical end of the cone better represents these known hazards when compared to a pull force applied perpendicular to the face of the rail.

(12) Instead of complying with section 8.4.4.3 of ASTM F3186-17, comply with the following:

(i) Under section 8.4.4.3, insert the 2.4 in (60 mm) end of the cone perpendicular into the opening. Slide the cone into the opening until it is in full contact with the product. The mattress shall only be compressed by the weight of the cone.

Rationale: The intent of this test is to address entrapment hazards associated with bed rails and head entrapment in Zone 2 by ensuring the test probe cannot pass through any openings in the entrapment zone. This criterion is based on the FDA guidance document, which includes a dimension of 120 mm (4.75 in), encompassing the 5th percentile female head breadth. This dimension is represented by the 4.7 in portion of the test probe, and it should be applied in any

orientation in which the head may be entrapped. The removed language may have led test personnel to unnecessarily restrict orientations that the probe may be applied.

(13) Instead of complying with section 8.4.4.4 of ASTM F3186-17, comply with the following:

(i) Under section 8.4.4.4, if the test probe does not pull through freely use the force gauge to exert a 22.5 lbf (100 N) pulling force along the axis of the cone, perpendicular to the 2.4 in (60 mm) cylindrical end of cone.

Rationale: The intent of this test is not to test the probe in both directions after being placed. It is to determine if both the 2.4 in and 4.7 in portions of the test probe cone can enter or pass through the Zone 2 opening under the required force. This would mean that a body part can be entrapped, and a hazard is present. Furthermore, applying the force perpendicular to the opening may have multiple interpretations, which may not always emulate the known hazard of head or limb entrapment. Applying the pull force perpendicular to the 2.4 in cylindrical end of the cone represents these known hazards better when compared to a pull force applied perpendicular to the face of the rail.

(ii) Under section 8.4.4.5, if a horizontal section of the rail greater than 4.7 in exists along the bottom of the rail, that section must also meet the Zone 2 requirements.

Rationale: During the development of the ABPR testing procedure, bed rails that have significant overhanging elements that would allow the passage of the head in a manner consistent with identified Zone 2 entrapment hazards were not considered. Due to the hazards being consistent with Zone 2, the requirements and test methods for these openings should be consistent as well.

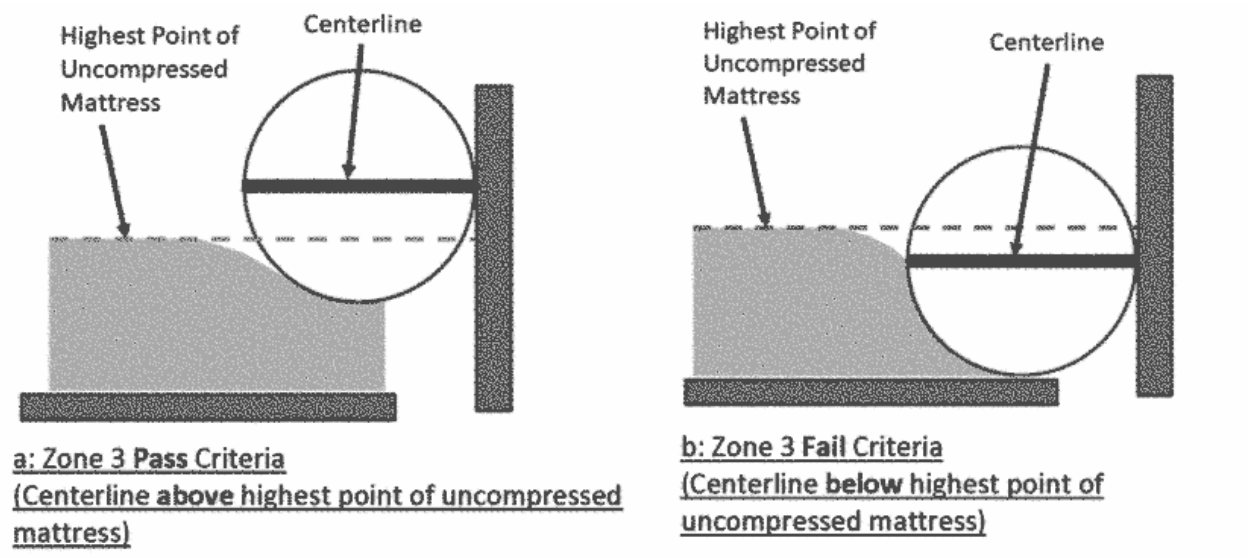
(14) Instead of complying with section 8.4.5.4 of ASTM F3186-17, comply with the following:

(i) Under section 8.4.5.4, turn the cone until the line on the face of the 4.7 in (120 mm) end is horizontal and let the cone sink into the space by its own weight.

(A) If the line on the face of the 4.7 in (120 mm) end of the cone is above the highest point of the uncompressed mattress, as shown in Figure 1 to paragraph (b)(14) of this section, the space passes the test.

(B) If the line on the face of the 4.7 in (120 mm) end of the cone is at or below the highest point of the uncompressed mattress, as shown in Figure 1 to paragraph (b)(14) of this section, the space fails the test.

Figure 1 to paragraph (b)(14) of this section: Zone 3 test: (a) Pass, (b) Fail



Rationale: The Zone 3 entrapment performance requirement in section 6.3.3 is redundant due to the failure criteria described in the associated test method, section 8.4.5.4. The failure criteria described in the test method is the intended requirement, which would also be more consistent with the FDA guidance document referenced in the standard and is the interpretation in favor of safety. In addition, the Figures are proposed to assist testers in visualizing the test criteria.[51]

(15) In addition to complying with section 8.6.3 of ASTM F3186-17, define "free end" in a note as follows:

Note 1 to Paragraph (b)(15)(i): The "free end" is defined as the location on the retention system that is designed to produce a counter force; it may be a single distinct point or a location on a loop.

Rationale: Section 8.6.3 requires a 50 lbf force to be applied to the "free end" of the retention system without adequately defining the term. This note will clarify the test method for testers and make it more repeatable. Adopting this note would make it "Note 4" and make the current Note 2, "Note 5" instead.

(16) Instead of complying with section 9.1.1.3 of ASTM F3186-17, comply with the following:

(i) Under section 9.1.1.3, that the product is to be used only with the type and size of mattress and bed, including the range of thickness of mattresses, specified by the manufacturer of the product. If beds with head or footboards are allowed, the distance between the head or footboard and the placement of the product shall be indicated to be >12.5 in (318 mm).

Rationale: This change addresses an inconsistency between 9.1.1.3, which states that products may be installed 12.5 in away from head or footboards, and 9.2.6, which states that products

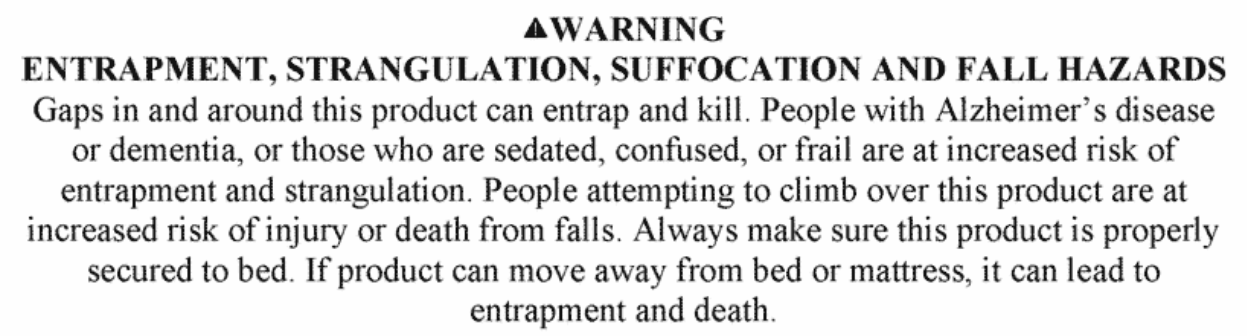
[51] The proposed Figure 4 would not replace the existing Figure 4 in the standard. The existing Figure 4 will be renumbered to Figure 5, and all citations will be adjusted accordingly.

must be installed at least 12.5 in from headboards or footboards. The revision TG has agreed to these changes, and they will be incorporated into the next revision of the standard.

(17) Instead of complying with section 9.2.5 of ASTM F3186-17, comply with the following:

(i) Under section 9.2.5, each product's retail package and instructions shall include the warning statements in Figure 2 to paragraph (b)(17)(i) of this section.

Figure 2 to paragraph (b)(17)(i): Warning Statements for Product Retail Package and Instructions

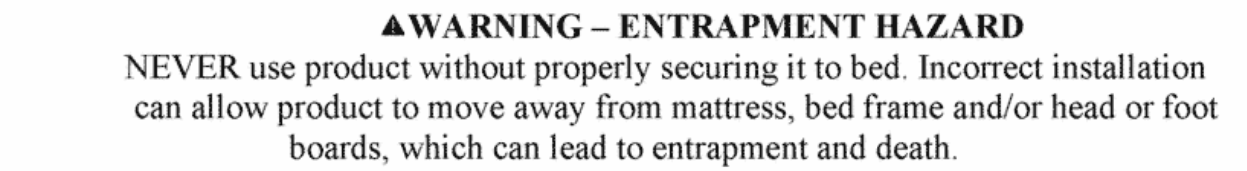


Rationale: This change is a grammatical edit and brings the warning language into alignment with similar language used in Section 9.2.6.

(18) Instead of complying with section 9.2.7 of ASTM F3186-17, comply with the following:

(i) Under section 9.2.7, at least one installation component of the product must be labeled with the entrapment warning in Figure 3 to paragraph (b)(18)(i).

Figure 3 to paragraph (b)(18)(i): Entrapment Warning



Rationale: The warning, as used in 16 CFR § 1224, is intended to draw attention to the installation component and to encourage its use. During the development of ASTM F3186, CPSC staff recommended that a similar requirement be added, and a draft of the voluntary standard included such a requirement. However, before publication of the voluntary standard, the requirement for this warning to be on an installation component was changed to say that it must be located on a "conspicuous component." The installation component is commonly located under the mattress during use, and therefore, the warning would not be "conspicuous" when in the manufacturer's recommended use position. Requiring the warning to be on a "conspicuous component" most likely would not permit the warning to be placed on an installation component. The proposed language would return the requirement to its original

intent, drawing attention to the installation component. The warning required by Section 9.2.6, which also discusses entrapment hazards and keeping the product tight against the mattress, is required to be placed on an installation component.

> **(19)** Instead of complying with section 11.1.1.3 of ASTM F3186-17, comply with the following:
>
> > **(i)** Under section 11.1.1.3, in addition to contacting the manufacturer directly, consumers should report problems to the CPSC at its website *SaferProducts.gov* or call 1-800-638-2772, or to the FDA at 1-800-332-1088.

Rationale: Editorial change, grammatical revision.

Staff's Response to Public Comments on the NPR

On November 9, 2022, the Commission published an NPR soliciting public comment on all parts of the NPR, including:

- Information regarding any analysis and/or tests done on APBRs in relation to the risks of injury or death they present;
- Information regarding any potential costs or benefits of the proposed rule that were not included the foregoing preliminary regulatory analysis;
- Information regarding the number of small businesses impacted by the proposed rule and the magnitude of the impacts of the proposed rule;
- The testing procedures and methods of the proposed rule and whether they sufficiently reduce the risk associated with APBRs, or whether other measures are necessary and information demonstrating how these measures address the identified risks;[52]
- Potential alternatives to APBRs if they are banned, and the impact that a ban on APBRs would have on consumers (e.g., lost consumer utility from not having the product);
- Any qualitative or quantitative evidence concerning the utility that APBRs have for consumers relative to alternative products that might be used as substitutes in the event APBRs are banned; and;
- The appropriateness of the 30-day effective date, and a quantification of how a 30-day effective date would affect the benefits and costs of the proposed rule.

CPSC received seven written comments during the comment period which ended January 9, 2023. The list of commenters along with their affiliations are provided in Table 11 below. CPSC did not receive any requests for oral comments related to the NPR. Any resulting changes, based on these comments, to staff's proposals for the draft final rule are included in the next section, Recommend Changes to the Final Rule Based on Comments.

[52] Staff Draft NPR, Tab F, Howie, A. Memorandum by CPSC Adult Portable Bed Rails Project Team, *Proposed Changes to ASTM F3186-17, Standard Consumer Safety Specification for Adult Portable Bed Rails and Related Products for NPR*, 2022.

Table 11: Public Comment Breakdown

Comment Number	Name	Affiliation
1	Sarina Marlin	Individual
2	Gloria Black	Individual
3	Louis A. Ferreira	Legal Representative for an Industry Member
4	National Center for Health Research (NCHR)	Nonprofit Thinktank
5	National Consumer Voice for Quality Long-Term Care (Consumer Voice)	Consumer Advocacy Group
6	Public Citizen	Consumer Advocacy Group
7	California Advocates for Nursing Home Reform (CANHR)	Consumer Advocacy Group

Below are summaries of the public comments received by topic followed by staff's responses.[53]

Comments on Banning APBRs

Comments: Four commenters addressed the issue of banning APBRs. Public Citizen strongly urged the CPSC to withdraw its proposed rule and promulgate a rule under section 8 of the Consumer Product Safety Act (CPSA), declaring all currently marketed adult bed rails to be banned hazardous products instead. NCHR, Consumer Voice, and CANHR commented that they do not support a ban at this time. However, they stated that they would support a ban on APBRs if the final rule is adopted and proves to be ineffective in preventing deaths and injuries resulting from APBR entrapment.

Staff Response: CPSC staff disagrees that a ban under section 8 of the CPSA is warranted. Under section 8 of the CPSA, 15 U.S.C. § 2057, to issue a ban, the Commission must find:

- a consumer product is being, or will be, distributed in commerce and such consumer product presents an unreasonable risk of injury; and
- no feasible consumer product safety standard under this Act would adequately protect the public from the unreasonable risk of injury associated with such product.

Staff finds the final rule, promulgated under section 9, which mandates compliance with the current voluntary ASTM standard, with modifications, will adequately address the unreasonable risk of fatal and non-fatal injuries related to APBR entrapment. Therefore, no change to the final rule is necessary based on this comment. Instead, staff recommends promulgating the final rule and, as data becomes available, assessing its efficacy.

[53] Public Comments on the NPR, in their entirety can be retrieved from: https://www.regulations.gov/document/CPSC-2013-0022-0110/comment

Comments on Alternatives to Using APBRs and on Qualitative or Quantitative Value of APBRs

Comments: Gloria Black, NCHR, Consumer Voice, Public Citizen, and CANHR identified several alternatives to using APBRs, such as: bed trapezes, adjustable beds, non-slip mattress pads, bed exit alarms, body pillows, and medical attendees.[54] Gloria Black specifically identified "no cost options" including lowering the bed or placing the mattress on the floor to prevent falls, placing cushioning on the floor to prevent serious injury, and placing a sturdy nightstand or table next to the bed to assist individuals in getting in and out of bed. Additionally, CANHR stated that APBRs are "used primarily as physical restraints for the convenience of others, and almost always unnecessary and in nursing homes" and per "the Nursing Home Reform Law of 1987's prohibition of physical restraints for the convenience of staff, safe alternatives to prevent injury from falls have been practiced for decades in compliant facilities."

Two comments addressed the qualitative or quantitative value of APBRs. Sarina Martin expressed a general concern that a ban on APBRs will increase the risk of falls in long-term care facilities. Consumer Voice was unaware of any qualitative or quantitative evidence concerning the utility that APBRs have for consumers relative to products that might be used as substitutes in the event APBRs are banned. However, Consumer Voice noted some consumers have expressed fears that a ban could limit their ability to leave their beds, lead to a decline in mobility and functioning and therefore increase their dependency, and result in decreased quality of life due to greater isolation.

Staff Response: Staff concludes that a ban on APBRs could leave consumers without a product that gives them mobility and independence. APBR products help these consumers by aiding them in safely staying in a bed and providing them with a safe grip for getting in/out of a bed and repositioning while in bed. Such products are particularly useful for consumers who live at their own personal residence, rather than a hospital or care facility, as supervision or assistance may be less readily available in a home environment. However, considering the number of fatal and non-fatal injuries, staff consider the requirements for APBRs in the draft final rule necessary to address the risks. Consumers may choose to use alternatives to APBRs, but these alternatives have been available to consumers, yet many injuries and deaths continue to occur. These alternatives alone have not adequately reduced the unreasonable risk of injury and death presented by APBRs, and the draft final rule is needed to address the identified hazards. Per the findings in Tab G of Staff's NPR briefing package and Section VI, A,2 of the NPR, staff concludes the draft final rule would not unduly limit the availability of APBRs.

Comments Regarding the Effect of the Proposed Rule on Long Term Care Facilities

Comment: Sarina Marlin expressed a general concern for the effect of the proposed rule on long-term care facilities. Ms. Marlin cites data from staff's NPR which indicates that a

[54] A bed trapeze is a product that consumers can use to get in out of bed or change position while in bed. It typically consists of a horizontal bar suspended from a metal frame. Bed trapezes are typically larger than adjacent-type bed rails and are therefore less portable.

disproportionate number of recorded fatalities associated with APBRs occur in home settings when compared to Long Term Care Facilities.

Staff Response: The fatality location ratios quoted by Ms. Marlin are drawn from the preamble of the NPR, in which staff identified 158, 50, 40, and 14 fatalities associated with APBR entrapment in homes, nursing homes, assisted living facilities, and residential institutions, respectively. However, one cannot infer that there are fewer fatalities per APBR in professional settings than in the home, or that APBRs in professional settings do not pose significant risk to the public, without knowing the number of APBRs in use in each setting. CPSC staff did not, and does not, possess this information nor data from which estimates of the number of APBRs in use in each setting may be drawn. No such information was submitted by commenters. However, given that APBRs are marketed primarily to individual consumers, staff assesses that APBRs are more likely to be found in the home than in professional settings.[55]

Staff found that a significant number of fatalities occurred in nursing homes, assisted living facilities, and residential institutions and has no information contradicting the sensitivity analysis done in the NPR which found significant net benefits for the proposed rule across a range of reasonable parameters and that the proposed rule was necessary to address these deaths.

Staff disagrees with the commenter that an undue impact will occur to long term care facilities. In the NPR's Preliminary Regulatory Analysis, CPSC staff considered the effect of the proposed rule on APBR price, the dead weight loss (the lost consumer and producer surplus resulting from price-induced decrease in APBR sales) associated with the price change, cost, and net benefits. Staff estimated the proposed rule would increase manufacturer costs in the first year by approximately $5.40 per APBR, of which $4.00 is expected to be passed on to APBR consumers (including commercial enterprises) in the form of higher prices. A $4.00 increase in APBR price represents less than 0.01 percent of the annual cost of a private room in an assisted living facility, and approximately half that already tiny percentage for a private room in a nursing home, which staff does not consider an undue burden for these facilities.[56] No change to the final rule is necessary based on this comment.

Comment on Hole Size Requirements

Comment: Louis A. Ferreira, of Stoel Rives, LLP, representing Stander, Inc., a seller of APBRs, suggests that the proposal to regulate the sizes of holes or slots that extend entirely through a wall section on an APBR is not reasonably necessary to prevent or reduce an unreasonable risk of injury. Mr. Ferreira disagreed with staff's proposal to make the opening requirements consistent with standards for other products such as Children's Portable Bed Rails and instead suggests that staff modify their proposal to simply correct the consistency errors in the existing standard. Mr. Ferreira claimed that "the size of the holes do not increase the risk of a fall of

[55] Professional care facilities may use a variety of products, including APBRs and hospital bed rails, depending on the needs of the patient.

[56] Genworth Financial, Inc., estimates the national median annual cost for a private room in assisted care facilities and nursing homes in the United States in 2021 at $54,000 and $108,405. Median Cost of Nursing Home, Assisted Living, & Home Care | Genworth.

entrapment" and that "There is not even evidence in the record that would support a conclusion that finger entrapment in the holes of an adult bed rail have ever caused an injury."

Staff Response: As reported in Tab A of the NPR briefing package, about 7,400 of the estimated 79,500 adult bed rail-related injuries treated in emergency departments from 2003 to 2021 were hand or finger injuries. Of these, about 3,400 were identified as injuries to fingers, most of which involved crushing or laceration.[57]

Section 6.4 of ASTM F3186 – 17 addresses the risk of finger entrapment and laceration in small holes or openings. Changes to this section are necessary to correct errors and inconsistent measurement references. Specifically, in stating the dimensions of the rods used to conduct testing, the standard inaccurately refers to 13 mm as the correct equivalent to 5/8 in. (5/8 in. is approximately 16 mm); and, while the standard allows different dimensions for holes or slots that do not exceed ¼ in. in depth, it refers to a drawing depicting a hole up to ".375 (9.53 mm) deep," or 3/8 in., shown below in Figure 2.

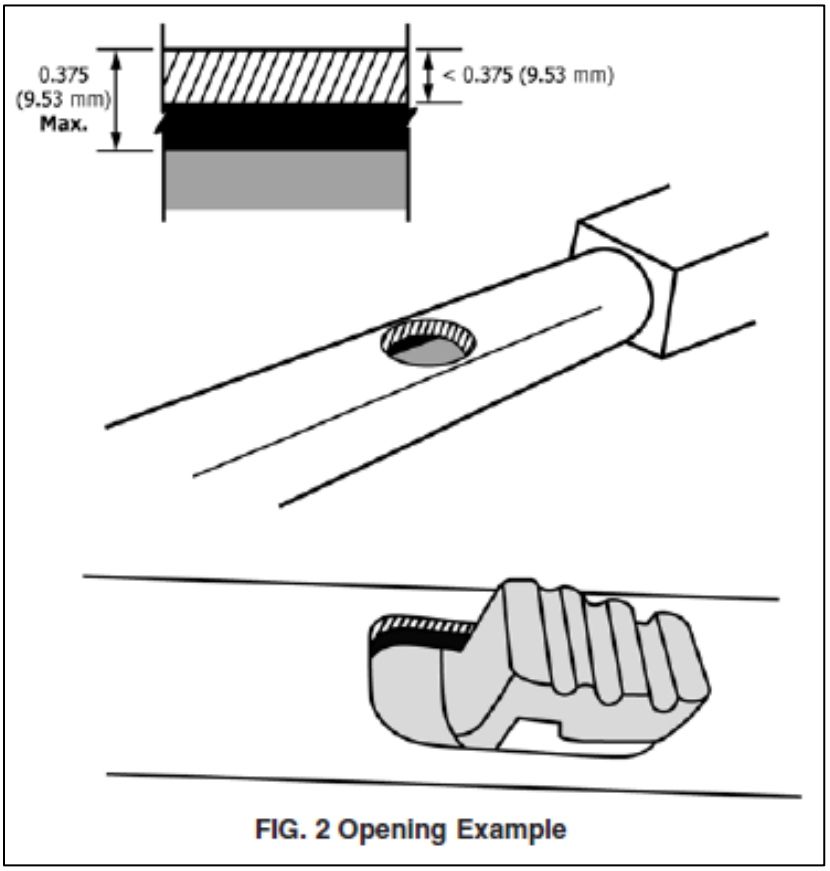


Figure 2: Illustration from Figure 2 of ASTM F3186 – 17, Section 6.4

[57] NEISS data can be queried by the public through the CPSC NEISS On-Line Query System - https://www.cpsc.gov/cgibin/neissquery/home.aspx

Further, the proposed changes in the NPR are necessary to adequately address the risk of injury because the hole dimensions referenced by the commenter are not effective in protecting vulnerable adult populations. Vulnerable adults are often smaller and more frail than other populations of adults and are more likely to use APBR products. The proposed changes in the NPR align the draft rule with established children's product regulations that prevent hazards to a range of finger sizes that covers both children and adult users simultaneously.[58]

Considering the points above, staff concludes the proposed language in the NPR is necessary to address the range of consumer exposure and the hazardous hole sizes relative to that range. No change to the final rule is necessary based on this comment.

Comment on Proposed Entrapment Test Modifications

Comment: Luis A. Ferreira, representing Stander, indicated that staff's proposed entrapment test modifications are ambiguous and inadequate. Stander expresses its concerns "that the ASTM Standard with the proposed modifications could be misinterpreted, and a product fail the test, not because of any unreasonable risk posed by the bed rail, but simply because a mattress is selected for testing that is so soft that the probe can be pulled beneath the bottom rail of the APBR." Stander goes on to suggest several changes to the proposed modifications to section 8.4 based on the following concepts:

- "make clear that if there is no vertical opening between the mattress and the bottom of the product, the product passes the test for Zone 2"
- "The concept of allowing the probe to compress the mattress using only the weight of the cone is a key part of the test specified by the ASTM Standard. This requirement is meaningless if the force gauge is attached from below the bottom rail even if there is no "opening" as identified in Section 8.4.4.2."
- "CPSC's proposal to modify the language of Section 8.4.4.5 is also ambiguous because it does not attempt to specify where to measure the 4.7 inches referenced."

Staff Response: ASTM F3186 – 17 does not have a specific definition for "Entrapment Zone". In the preamble of the NPR, staff referenced FDA guidance as well as staff findings from the incident data to explain what an entrapment zone is and what the different entrapment zones related to APBRs are. However, per the commenter's interpretation of the entrapment test methods, it is clear the voluntary standard does not adequately describe what an Entrapment Zone is and why it is tested.

Each entrapment zone test addresses specific hazard patterns which are identified in both the FDA guidance document as well as staff's findings from the incident data. The hazard patterns associated with each entrapment zone are described below.

[58] It is also foreseeable that children may interact with APBRs, such as when visiting grandparents. Adopting staff's proposed modifications to the voluntary standard would also protect children without creating any new hazards for adults.

- Zone 1 testing addresses head-first entry into fully bounded openings within the structure of the rail.
- Zone 2 testing addresses head-first entry under the rail into any opening between the mattress compressed by the weight of a consumer's head and a section of the bedrail longer than 4.7 in.
- Zone 3 testing addresses entry of the head into a gap between the inside surface along the length of the rail and the mattress compressed by the weight of a consumer's head.
- Zone 4 addresses neck-first entrapment, between the rail and mattress compressed by the weight of a consumer's head and neck at the ends of the rail.

Staff disagrees with Stander's interpretations that entrapment zone hazards only exist where there are visible openings. According to the CPSC's analysis of the incident data, the area "between the rail and mattress" is the most common location for entrapment. The hazards related to each zone are present regardless of the locations of the supports but are dependent on the shape of the rail in relation to the anthropometric dimensions of the user.

For example, per Zone 2, the known hazard is head-first entry under the rail in any section longer than the anthropometric head dimension of the entrapment test probe, which is 4.7 inches. Therefore, in Figure 3 below, both the red and blue areas should meet Zone 2 requirements, in addition to the other applicable tests, to ensure the product adequately addresses the known hazard.

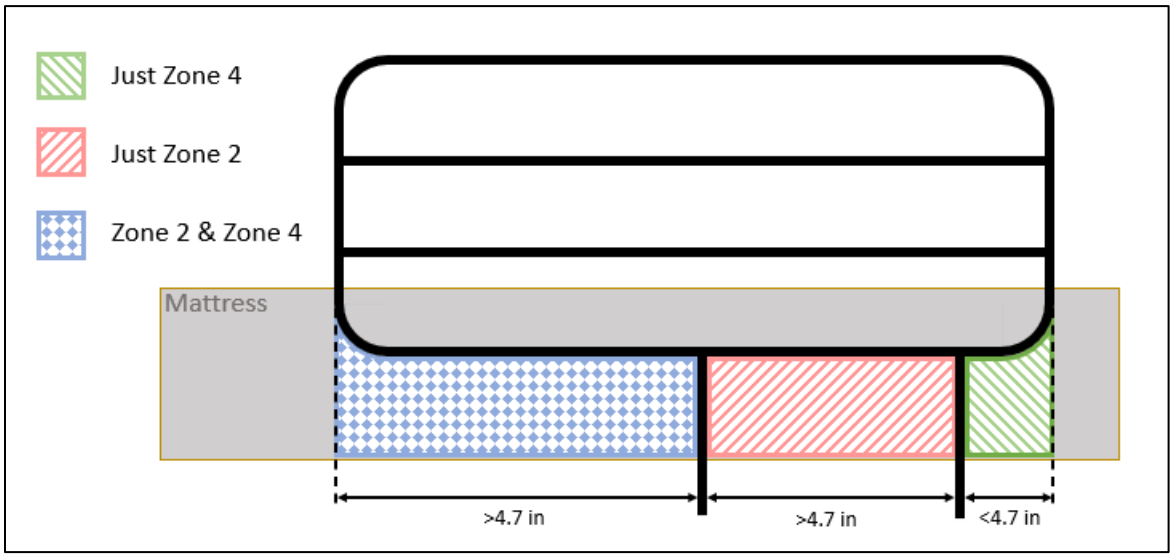


Figure 3: General example of areas subject to Zone 2 requirements.

Safety testing should represent known hazard modes, including the displacement caused by consumers moving or pushing into the mattress or product which may create an opening that was not previously visible. During entrapment zone testing, the positioning and application of the force via a force gauge must be realistic and representative of all reasonably foreseeable

scenarios of consumer behavior. In many cases, applying the force to the probe by attaching a force gauge below the bottom of the rail is the most accurate representation of the worst case of this foreseeable hazard scenario. Additionally, in contrast to the current voluntary standard, entrapment hazards are not present only in the "largest opening" of a product. Entrapment hazards may exist in several areas depending on the product configuration and installation.

To ensure entrapment hazards are adequately addressed, products must be assessed in all areas which may constitute an entrapment zone. Therefore, staff recommend modifications to the language in each entrapment zone testing section to make this more evident. In response to this comment, staff will recommend to the Commission that the language in the final rule be amended as follows:

- Adding a global definition for "Entrapment Zone" to the draft rule, which will clarify what areas must be tested.
- Removing language from the test methodology that may have led test personnel to unnecessarily restrict locations and orientations of the placement of the entrapment test probe for testing.
- Improving instructions for test personnel to apply forces in a manner that is more representative of the entrapment hazards.

Comment on Removing Mattress Thickness Selection for Testers

Comment: Louis A. Ferreira, representing Stander, suggests that CPSC's proposal to add Section 7.1.3 to the voluntary standard's requirements is not reasonably necessary to prevent or reduce an unreasonable risk of injury. Staff's proposal for this additional section would allow testers to select a mattress for testing that is up to 1.5 in (38 mm) thicker or thinner than the range specified by the manufacturer. Mr. Ferreira asserts that staff's rationale for this proposal is unfounded and that "there is no evidence in the record that a consumer has ever suffered an injury because they used an adult bed rail on the wrong size mattress."

Staff Response: Mattress thickness has a direct bearing on the entrapment hazard. As shown above in Table 7, ASTM F3186 – 17 defines Zones 2, 3, and 4 in relation to the product and the mattress. A mattress that is too thin can result in larger entrapment zones, posing a greater risk of entrapment. Additionally, a mattress that is too thick will not meet the standard's structural integrity performance requirement, found in Section 6.2, states that the top of the bed rail must extend 4 inches above the mattress.

APBR manufacturers rely on warnings, labeling, and instructional literature to convey information on the mattress thicknesses that can safely be used with an APBR. For adjustable products, additional information is required on how to select product settings that minimize hazards when installed on a compatible mattress.

As staff discussed in the draft NPR briefing package, warnings and instructions have a limited effectiveness in preventing hazards. Consumers do not always read, understand, and heed this information. Mattress "compatibility" with an APBR is strictly nominal, staff has found that most

APBR models can be installed and adjusted regardless of mattress thickness, and the hazard created by using an APBR on an incompatible mattress will not be apparent to the typical consumer. Therefore, it is preferable to design out hazards rather than rely on consumers to follow warnings and instructions.

It is foreseeable that some consumers will use APBRs with mattresses that are not within the manufacturer's recommended thickness range. It is unlikely that consumers will fully understand the relationship between mattress thickness and the entrapment hazard, regardless of the information found in instructions and warnings. Consumers who rely on the nominal measurement found on mattress packaging or labels may not be aware of the true thickness of the mattress. During APBR testing, staff has found that a mattress's true thickness typically differs from the thickness advertised by the mattress manufacturer. Consumers are unlikely to measure their mattress prior to purchasing an APBR, or they may not measure accurately. Consumers may not have information about the mattress thickness when they purchase APBRs for use by another person, or for use on a hotel or guest bed. Consumers who transfer existing APBRs to a new mattress may not take any action to ensure that the mattress is the appropriate thickness for the APBR.

The mattress thickness variability requirements in the draft final rule encourage manufacturers to anticipate these and similar foreseeable scenarios. The requirement covers a limited range of mattresses beyond what is advertised to account for the known hazards outside of the "compatible" range.

Comment on Language Modifications for Mattress Thickness Selection

Comment: Consumer Voice notes some contradictions between the proposed modifications to the voluntary standard and existing sections within the current standard that would potentially allow manufacturers to avoid providing consumers a recommended mattress thickness range for their products. Consumer Voice requested to have this language removed in the final rule.

Staff Response: Staff agrees with Consumer Voice. Section 9.1.1.3 of the voluntary standard requires manufacturers to list a recommended thickness range. Staff's revised proposal for the draft final rule will remove "If the manufacturer does not recommend" and other related language from the proposed additions to sections 6.2.1 and 7.1. Instead, both sections will provide general guidance for test personnel.

Comment on Banning Retention Straps

Comment: Consumer Voice requested staff ban the use of straps as a means of attaching the product to a bed. Consumer Voice asserts that the use of straps as a means to attach an APBR to a bed greatly increases the risk of improper assembly and the likelihood of harm, and that straps can stretch and become loose over time.

Staff Response: Staff considers retention straps to be an acceptable means of securing ABPRs to beds. Banning retention straps would unnecessarily restrict APBR designs and could impose an unreasonable burden on manufacturers and consumers. The proposed modifications to the requirements of the standard, such as the requirement for a warning on an "installation

component", will adequately address known hazards associated with APBRs and increase the likelihood of consumers installing the retention strap. Staff have not identified any hazards specifically associated with retention straps, such as strap strangulation, and therefore does not have sufficient evidence to support banning retention straps.

Comment on Modifying the Proposed Definition of "Conspicuous"

Comment: Consumer Voice states their concerns that the proposed definition of "Conspicuous", as defined in Section 3.1.3 of the voluntary standard, is too narrow, Consumer Voice suggests staff modify the proposed definition to increase the requirements for visibility of warning labels on the product. Specifically, Consumer Voice recommends that the definition be revised so that "conspicuous" labels/components be visible to both the consumer and a person standing near the unit from at least two different positions.

Staff Response: Staff's proposed definition of "Conspicuous" remains as written in section 3.1.3 of ASTM F3186 – 17. The definition requires certain labels to be visible from one position rather than 2 positions, as proposed by the commenter. Staff assesses that the commenter's recommended alternative definition of "Conspicuous", as written, does not provide sufficient guidance regarding the two positions in which warning labels would be required to be visible, and that the definition could foreseeably be interpreted such that two viewing positions are only marginally different. Therefore, staff asserts that the commenter's proposed definition does not represent a substantive improvement to safety and finds insufficient justification for the change.

Comment on Adding "Conspicuous" to Warning Labeling Requirements

Comment: Consumer Voice recommends that the term "conspicuous" should not be deleted from the warning label placement requirements in section 9.2.7. Consumer Voice claims the removal of the word would weaken the requirement and make the product less safe.

Staff Response: As discussed in the NPR briefing package, the warning in section 9.2.7 was originally intended to draw attention to the installation component and encourage its use (16 CFR 1224, the children's bed rail standard, has this same warning and requires it to be on an "installation" component). Additionally, other warnings addressing entrapment hazards and securing the APBR to the bed are required to be placed on a conspicuous component of the product and/or packaging/instructions. However, the warning in section 9.2.7 is directly related to product installation, whereas the other warnings address other topics. Therefore, staff maintains that the warning in section 9.2.7 should be on an installation component.

Comment on Making Compliance Testing Records Publicly Available

Comment: Although Consumer Voice is pleased that the proposed rule would require manufacturers to retain records of compliance testing, Consumer Voice requests an additional requirement that manufacturers provide consumers with records of compliance testing upon request.

Staff Response: Manufacturers and importers of APBRs will already be required to issue a General Certificate of Conformity (GCC) under Section 14 of the CPSA and 16 C.F.R. part 1110 for the APBR mandatory standard. A GCC requires manufacturers or importers to certify that

their general use products comply with all applicable consumer product safety rules (or similar rules, bans, standards, or regulations) under any law enforced by the Commission for that product. GCCs must be based on a reasonable testing program. A GCC must "accompany" the applicable product or shipment of products covered by the certificate. A manufacturer or importer must "furnish" the GCC to distributors or retailers, however there is no requirement to provide records of compliance testing to consumers. Thus, firms must comply with all of the GCC requirements in section 14 of the CPSA. Based on the available information staff has not found significant evidence indicating that the proposed requirement, on manufacturers to provide records of compliance testing directly to consumers, will substantially decrease the known hazards related to APBRs given the existing GCC framework.

Comment on Reorganizing Labeling Requirements

Comment: Consumer Voice argues that the labeling and warning requirements for retail packaging, instructions and the product labels set out in the proposed rule are confusing and contradictory. Consumer Voice specifically suggests reorganizing the labeling requirements to address retail packaging, instructions, and product labels, separately.

Staff Response: Staff does not agree with Consumer Voice's proposed change to the final rule. Staff concludes that the current requirement in the voluntary standard ASTM F3186 – 17, that is incorporated by the draft final rule, clearly states the required location for each warning.

Comment on Adding Labeling Requirements for Intended Use

Comment: Consumer Voice suggests adding labeling requirements to include information about the intended use of APBRs and who the products are designed for.

Staff Response: Staff agrees that APBR manufacturers should specify how their product(s) function in their instructions and on their product packaging. However, staff's familiarity with existing ABPRs' marketing, packaging, labeling, and appearance leads staff to assess that consumers are likely to understand that the products are designed for elderly users and/or adult users with disabilities/inhibited movement, so the additional recommended labeling is unnecessary.

Comment on Adding Email Address to Contact Information Requirements

Comment: Consumer Voice argues that email is an increasingly used form of communication, and including an email will make contacting manufacturers more accessible for consumers. Consumer Voice requests that the final rule should require manufacturers to include their email address in addition to the other contact information currently required.

Staff Response: Staff believes that the required contact information already in the standard is adequate for consumers to get in contact with the manufacturer. Staff do not have any evidence indicating that requiring an email address will decrease known hazards related to APBR products.

Comment on Adding Language to Warning Statements

Comment: Consumer Voice suggests adding to the language throughout the final rule's warning statements. Consumer Voice suggests including a discussion of the risk of "serious injury or death from entrapment."

Staff Response: Staff finds the comment proposal to be unnecessary and lacking data to support a change from the proposed warning language. Each warning clearly states that improper use and/or installation can lead to entrapment and death. Staff assesses that no change to the final rule is necessary based on this comment.

Comment on Adding Drawings in Instructional Literature Requirements

Comment: Consumer Voice recommends requiring manufacturers to include drawings in the instructions that depict potential examples of entrapment to allow consumers to better understand the potential hazards of APBRs.

Staff Response: Section 11.1 of the APBR voluntary standard, ASTM F3186-17 already includes a similar requirement and would be incorporated by reference in the draft final rule. Per the requirement, manufacturers are required to include drawings of all entrapment zones (zones 1-4). The FDA drawings are provided as a reference in Appendix X1.1 but manufacturers are free to use their own illustrations should they choose to do so.

Comments Regarding Stockpiling

Comments: Consumer Voice and CANHR, submitted comments in favor of the stockpiling provision proposed in the NPR.

Staff Response: No comments objecting to the proposed stockpiling provision were submitted, therefore staff recommends keeping the proposed prohibition on stockpiling.

Comments Regarding Effective the Date

Comments: Three commenters submitted comments regarding effective dates. Consumer Voice and CANHR were in favor of the 30-day effective date. Louis A. Ferreira, representing Stander, urged that the effective date provision be modified so as to allow a one-year period to sell existing stock of APBRs that are compliant with the ASTM F3186 – 17 standard.

Mr. Ferreira states that, "Stander has made a significant investment to produce product consistent with the existing ASTM Standard," and that "… it would require a least a year to sell its existing stock that is compliant with the existing ASTM Standard but not the modified ASTM Standard …" Mr. Ferreira further states that, "As the CPSC has found the compliance with the existing ASTM Standard is sufficient to eliminate the 'unreasonable' risks posed by APBRs, CPSC should expressly allow manufacturers a reasonable period of time to sell existing stock that complies with the current ASTM Standard" and that "Stander believes that a reasonable period to sell its ASTM Standard compliant stock would be one year."

Consumer Voice considered the 30-day effective date to be appropriate and fair, and stated that "manufacturers should not need more than 30 days." They also commented that the ASTM

standards went into effect in 2017 and that "Five years is more than enough time to understand the standards and take the steps necessary to comply." CANHR stated "For the reasons the Commission cites, we support the staff's recommendation not to issue the new rule with an introduction time more than 30 days" while also noting that the ASTM voluntary standard has been available since 2017.

Staff Response:

No commenter contends that a 30-day period is insufficient for manufacturers to come into compliance with the draft final rule. And the draft rule itself resolves Stander's concerns regarding the effective date. As stated in the NPR, the proposed § 1270.1 Scope, application, and effective date, states, "…part 1270 establishes a consumer product safety standard for adult portable bed rails manufactured after 30 days after publication of the final rule in the Federal Register." Therefore, APBRs manufactured prior to the regulation's effective date are not required to comply with the standards set forth in the final rule. However, Stander and other manufacturers will be subject to the anti-stockpiling provision, which limits the number the APBRs that can be manufactured during the period between the final rule's publication and the effective date.

Finally, for clarity, staff disagrees with Mr. Ferreira's claim that "the CPSC has found the compliance with the existing ASTM Standard is sufficient to eliminate the 'unreasonable' risks posed by APBRs …" As stated in preamble of the NPR, and also described in the NPR briefing package, "the Commission preliminarily determines that the voluntary standard is not likely to eliminate or adequately reduce the unreasonable risk of injury associated with entrapments on APBRs." In 87 Fed. Reg. 67,586, the NPR, the Commission preliminarily determined the combined requirements of the voluntary standard—*with the proposed modifications that were deemed necessary*—would adequately reduce unreasonable risk and injury associated with APBR entrapment. Therefore, the Commission did not find the voluntary standard by itself sufficient to address the unreasonable risk posed by APBRs.

Recommended Changes to the Final Rule Based on Comments

Based on the comments received, staff recommends several changes to the proposed language in the NPR for the draft final rule. The recommended changes are intended to clarify certain sections and improve safety in ways such as:

- Adding new definitions to ensure consistency throughout the rule.
- Improving requirements for manufacturers to inform the consumer of the range of compatible mattress thicknesses to ensure safe use of the product and to provide testers with guidance for selecting the correct mattress thickness during the test setup.
- Updating the requirements for entrapment testing to be consistent with known hazards.

The following sections highlight staff's recommended changes to the proposed § 1270.2(b) in the draft final rule. Recommended changes to the proposed rule are shown in red text. Underlined sections are to be added, and sections that are struck through are to be removed.

Staff's rationale is provided for all recommended changes to the draft final rule. A comprehensive list of all the necessary modifications to ASTM F3186 – 17 for the draft final rule is included in Tab B of this briefing package.[59]

Additional Definition

ASTM F3186 – 17 does not define "Entrapment Zone". In the preamble of the NPR, staff referenced both the FDA guidance document and incident data to determine what the entrapment zones are, and the different ways entrapment could occur within them. In response to the NPR, staff received a comment on proposed entrapment test modifications which contradicted the known entrapment zone hazards. Therefore, staff recommends that the final rule includes an additional definition for "entrapment zone" as described below.

- Staff recommends revising the proposed rule in the final rule to add the following new definition to § 1270.2(b)(1):

In addition to complying with the definitions in section 3.1 of ASTM F3186 – 17, comply with the following definition:

> **(i)** *3.1.5 Entrapment Zone*, n- An area, gap, or opening that can potentially capture or restrain a person's body part. Hazardous openings may not always be visible prior to testing.

Rationale: ASTM F3186 – 17 does not formally define what an entrapment zone is. This global definition for the final rule will provide this necessary information and will lead to more consistent interpretations for what an entrapment zone is and where they can be found for testing.

Amendments for Test Mattress Selection

Based on a comment received regarding modifications to the language for mattress thickness selection, staff recommends removing language in the proposed rule that could be interpreted as exempting manufacturers from including a range of compatible mattress thicknesses which is contradictory to the intent of the standard.

- Staff recommends revising proposed § 1270.2(b)(3)(i) as follows in the final rule:

In addition to complying with the requirements for structural integrity in section 6.2.1 of ASTM F3186 – 17, comply with the following:

> **(i)** Under section 6.2.1.1, ~~If the manufacturer does not recommend a specific applicable range of mattress heights or thicknesses, t~~The test personnel shall choose a mattress and product setting configuration that ~~provides~~ results in the most severe condition per test requirement (see 7.1.3). ~~If the product has adjustable settings, and the manufacturer does not recommend orienting or adjusting features on the product in a~~

[59] Staff Draft FR, Tab B, Howie, A. Memorandum by CPSC Adult Portable Bed Rails Project Team, *Proposed Changes to ASTM F3186-17, Standard Consumer Safety Specification for Adult Portable Bed Rails and Related Products for FR*, 2023.

~~specific manner, the testers may choose to adjust the product to the most severe condition per test requirement~~

Rationale: Defining a range of recommended mattress thicknesses provides consumers with necessary information for the safe use of the product. Similarly, products may come with many types of adjustable settings and consumers may incorrectly assume all settings are safe for any given mattress. Selecting the mattress and product setting which provide the most severe conditions for each test will ensure that all hazards are adequately addressed. This requirement is supplemental to the misassembly requirements in section 6.5. Modifications to the originally proposed language were made based on a comment received in response to the NPR. The commenter indicated that the original proposed language seemed to create an alternative requirement for manufacturers who do not provide a recommended thickness range, as required by section 9.1.1.3 of the voluntary standard.

- Staff recommends revising proposed § 1270.2(b)(8)(i) as follows in the final rule**:**

In addition to complying with the test platform requirements in section 7.1 of ASTM F3186 – 17, comply with the following:

(i) Under section 7.1.3, mattress thickness ranges used for testing ~~may~~ shall be up to 1.5 in (38 mm) larger or smaller than the range specified by the manufacturer. ~~If the manufacturer does not recommend a particular range of mattress heights, the testers~~ The test personnel shall choose a mattress and product setting configuration that provide~~s~~ the most severe condition ~~per test requirement~~ for each test requirement in the standard.

Rationale: Consumers are not necessarily expected to measure mattress thickness, nor are they expected to purchase a new mattress for proper compatibility. Additionally, consumers are likely to follow general descriptions of their mattresses which may vary from the actual specifications. Adding this additional range will increase safety by accounting for foreseeable differences between nominal and actual mattress thicknesses, as well as consumer selection which may deviate from manufacturer recommendations. Modifications to the originally proposed language were made based on a comment received in response to the NPR. The commenter indicated that the original proposed language seemed to create an alternative requirement for manufacturers that do not provide a recommended thickness range, as required by section 9.1.1.3 of the voluntary standard.

Amendments to Entrapment Testing

Based on the comments received related to entrapment testing, staff recommend additional amendments to ensure the test methodology properly addresses known hazard modes that occur during use. Staff recommends the following changes to align the testing with the new entrapment zone definitions, remove language that may have led test personnel to unnecessarily restrict locations and orientations of placing the entrapment test probe, and instruct test personnel to apply forces in a manner that is more representative of the entrapment hazards.

- Staff recommends revising proposed § 1270.2(b)(11)(i) as follows in the final rule:

Instead of complying with the current requirements for entrapment Zone 1 testing in section 8.4.3.4 of ASTM F3186 – 17, comply with the following:

> **(i)** Under section 8.4.3.4, if the test probe does not pull through~~,~~ freely, attach the force gauge and exert a 22.5 lbf (100 N) pulling force ~~along the axis of the cone, perpendicular~~ to the 2.4 in (60 mm) cylindrical end of the entrapment test tool in the direction most likely to lead to failure of the requirement ~~perpendicular to the plane of the opening in both directions~~. If the 4.7 in (120 mm) end of the cone does not enter any of the openings, this space passes the test. If the 4.7 in (120 mm) end of the test probe cone does enter any of the openings, this space fails the test.

Rationale: The intent of this test is to determine if both the 2.4 in and 4.7 in portions of the test probe cone can enter and pass through any Zone 1 opening under the required force, which would indicate an entrapment hazard. In response to the NPR, a commenter proposed alternative entrapment testing methods and interpretations that limit the orientation of the test probe and application of force in a way that would not represent known entrapment hazards. The proposed language has been modified to remove restrictions on how the probe and force should be applied to better represent the known hazards and ensure consistent interpretations of the test methods. Applying the force perpendicular to the 2.4 in end of the probe may not always emulate the known hazard of head or limb entrapment. The amended language "in the direction most likely to lead to failure of the requirement" is clearer and more commonly understood by safety testing personnel.

- Staff recommends revising proposed § 1270.2(b)(12)(i) as follows in the final rule:

Instead of complying with the current requirements for entrapment Zone 2 test setup in 8.4.4.3 of ASTM F3186 – 17, comply with the following:

> **(i)** Under section 8.4.4.3, insert the 2.4 in. (60 mm) end of the cone ~~perpendicular~~ into the opening at the angle most likely to allow it to pass through. ~~Slide~~ Insert the cone into the opening until it is in full contact with the product. The mattress shall only be compressed by the weight of the cone.

Rationale: In response to the NPR, a commenter proposed alternative entrapment testing methods and interpretations that limit the orientation of the test probe and application of force in a way that would not represent known entrapment hazards. The proposed language has been modified to remove restrictions on how the probe and force should be applied to better represent the known hazards. The intent of this test is to address entrapment hazards associated with bed rails and head entrapment in Zone 2 by ensuring the test probe cannot pass through any openings in the entrapment zone. This criterion is based on the FDA guidance document, which includes a dimension of 120 mm (4.75 in), encompassing the 5th percentile female head breadth, which represents the smallest and most at-risk consumers who will foreseeably use APBRs. This dimension is represented by the 4.7 in portion of the test probe, which should be applied in any orientation in which the head may be entrapped.

- Staff recommends revising proposed § 1270.2(b)(13)(i) as follows in the final rule:

Instead of complying with the current requirements for entrapment Zone 2 testing section 8.4.4.4 of ASTM F3186 – 17, comply with the following:

> **(i)** Under section 8.4.4.4, if the test probe does not pull through freely use the force gauge to exert a 22.5 lbf (100 N) pulling force ~~along the axis of the cone, perpendicular~~ to the 2.4 in (60 mm) cylindrical end of the cone in the direction most likely to lead to failure of the requirement.

Rationale: In response to the NPR, a commenter proposed alternative entrapment testing methods and interpretations that limit the orientation of the test probe and application of force in a way that would not represent known entrapment hazards. The language has been modified to remove restrictions on how the probe and force should be applied to better represent the known hazards. The intent of this test is to determine if both the 2.4 in and 4.7 in portions of the test probe can enter or pass through the Zone 2 opening under the required force. This would mean that a body part can be entrapped, and a hazard is present. Removing restrictions on how the force should be applied better represents the known hazards. Applying the force perpendicular to the 2.4 in face of the probe may not always emulate the known hazard of head or limb entrapment. Applying the pull force in the direction most likely to lead to failure of the requirement represents these known hazards better when compared to a pull force applied perpendicular to the face of the rail.

- Staff recommends revising proposed § 1270.2(b)(13)(i) as follows in the final rule:

In addition to complying with section 8.4.4, Zone 2 testing locations, of ASTM F3186 – 17, comply with the following:

> **(ii)** Under section 8.4.4.5, if an entrapment zone greater than 4.7 in exists along the bottom of the rail, that section must meet the Zone 2 requirements regardless of the number or location of the supports. Repeat testing described in sections 8.4.4.3 and 8.4.4.4 for all applicable entrapment zones. Figure 1 below shows a general example of areas subject to Zone 2 requirements.

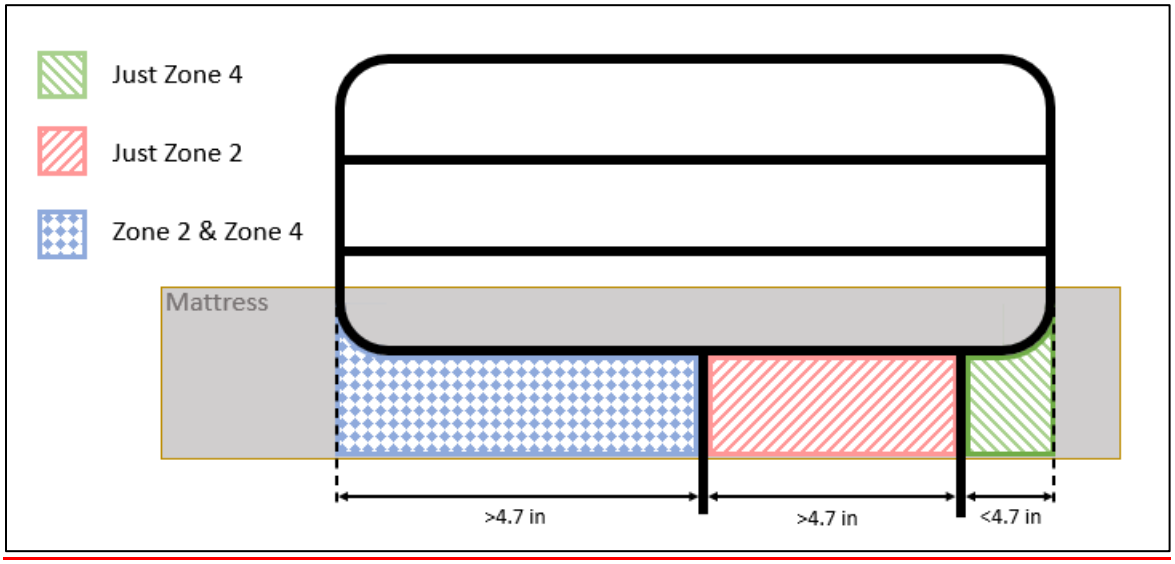


Figure 1: General example of areas subject to Zone 2 requirements.

Rationale: In response to the NPR, a commenter brought up concerns about the location of zone 2 on bed rails with multiple supports. Zone 2 testing is meant to address head-first entry under the rail into any opening between the mattress compressed by the weight of a consumer's head and a section of the bedrail. Bed rails that have overhanging elements longer than 4.7 inches can allow the passage of the head in a manner consistent with identified Zone 2 entrapment hazards regardless of the number or location of vertical support rails. 4.7 inches is the diameter of the test probe and encompasses the 5th percentile female head breadth. This language and figure clarify all areas that should be included in Zone 2 testing.

Economic Analysis for the Final Rule on Adult Portable Bed Rails

CPSC staff from the Directorate for Economic Analysis (EC) have not identified any meaningful changes in the APBR market or data used for the analysis of benefits and costs since the last economic analyses written for the NPR, published on November 9, 2022. The NPR included both a Preliminary Regulatory Analysis and an Initial Regulatory Flexibility Analysis.[60,61] This briefing package includes a Final Regulatory Analysis and Final Regulatory Flexibility Analysis which incorporate the previous analyses in the NPR.[62,63]

[60] Staff Draft NPR, Tab G, Row, R. Memorandum by The Directorate for Economic Analysis, *Adult Portable Bed Rail Preliminary Regulatory Analysis,* 2022

[61] Staff Draft NPR, Tab H, Row, R. Memorandum by The Directorate for Economic Analysis, *Adult Portable Bed Rail Initial Regulatory Flexibility Analysis,* 2022.

[62] Staff Draft FR, Tab C, Row, R. Memorandum by The Directorate for Economic Analysis, *Final Regulatory Analysis Memorandum,* 2023

[63] Staff Draft FR, Tab D, Row, R. Memorandum by The Directorate for Economic Analysis, *Adult Portable Bed Rail Final Regulatory Flexibility Analysis,* 2023.

This section summarizes the information in the Final Regulatory Analysis and Final Regulatory Flexibility Analysis.

Adult Portable Bed Rail Market Size

Staff identified 12 firms supplying as many as 65 total APBR models. Staff estimated overall APBR market revenues in the United States to be between $6 million and $9 million at 2021 retail prices, and volumes to be between 40,000 and 182,000 units. Based on an interview with an APBR manufacturer's representative, staff considers the higher end of these sales and volume ranges, $9 million in revenues and 180,000 units sold, to more accurately reflect the actual APBR market size.

Analysis of Potential Benefits and Costs

Benefit Analysis

To determine the potential benefit that may be gained by adopting the draft final rule, staff calculated the reduction in societal costs by estimating the number of deaths from entrapment and strangulation that would be prevented through compliance with the proposed rule. Staff did not include injuries in its benefit-cost assessment. As described in the incident data and hazard analysis section above, unlike the reported deaths, for many of the incidents reporting injuries, there was not enough information to determine whether they would fall within the scope of this draft final rule. Specifically, in many cases, staff was unable to determine if the nonfatal injury was caused by an APBR or some other type of bed rail. Staff was also unable, in many cases, to determine a specific cause of the injury. However, in the NPR sensitivity analysis, Section VI. A. 3, staff did quantify and monetize the injuries using the CPSC's Injury Cost Model (ICM), and by making assumptions about the potential share of incidents that would fall under the scope of the rule, illustrate a potential upper limit to the benefits of this draft final rule.

Staff forecast the number of expected deaths over a 30-year period from 2024 through 2053 and converted the value of prevented fatalities into monetary terms using the Value of a Statistical Life (VSL).[64] Staff forecast deaths by applying an estimated death rate per million APBRs to the estimated APBRs expected to be in use for each year of the 30-year period of analysis. Furthermore, staff considers the projected growth rate of the home health market and the changing demographics in the United States, and how these considerations impact APBRs' target market population throughout the 30-year period when estimating APBRs in use, and subsequently, deaths from those APBRs.

To estimate the societal costs of entrapment and strangulation-related deaths, staff applied the VSL estimate developed by the U.S. Environmental Protection Agency (EPA). The EPA estimate of the VSL inflated to 2021 dollars is $10.5 million.[65] Staff multiplied the VSL by the

[64] A 30-year period allows for several cycles of useful life for APBRs and ensures the benefits assessment accounts for any latent, long-term, and refresh effects from the draft proposed rule.

[65] In 2008, the EPA estimated the value per statistical life at $7.9 million. CPSC staff adjusted this estimate for inflation to the end of 2021, using the Consumer Price Index for All Urban Consumers (CPI-U) estimated the Bureau of Labor Statistics and rounded it

number of forecasted deaths over the next 30-year period to calculate the societal cost of deaths from entrapment and strangulation in the absence of the proposed rule.

While staff has concluded that the proposed rule will address falls and other miscellaneous hazard modes, the scope of ASTM F3186 – 17 is specifically intended to address entrapment and strangulation hazards associated with APBRs. Therefore, CPSC staff's benefits analysis assumes the draft final rule will address only 92 percent of reported deaths (*i.e.*, deaths related to entrapment and strangulation hazards) if the products operate as expected.[66] However, the effectiveness of the draft final rule depends, to some extent, on consumers installing the product correctly. The draft final rule provides significant improvements designed to help consumers; however, there may still be some injuries and deaths resulting from improper installation of APBRs or installation on mattresses that, due to their thickness, are inappropriate for the product. CPSC staff cannot provide a precise measure of effectiveness of the draft final rule. Therefore, to assess potential benefits, staff considers three scenarios with three different levels of effectiveness: 75 percent, 50 percent, and 25 percent of achievable benefits. Staff chose these levels as a stress test for the draft final rule to determine how its benefits compared to its costs, even under a very conservative assumption of a 25 percent effective rate. Staff estimates the annualized benefits of the draft final rule under these three scenarios, assuming an annual discount rate of 3 percent and in 2021 dollars, to be $200.24 million, $133.49 million, and $66.75 million, respectively.

Cost Analysis

Like the benefits estimate, the time span of the cost analysis covers a 30-year period. The cost analysis presents all cost estimates in 2021 dollars. This cost analysis also discounts costs in the future to their present value, using a 3 percent discount rate.[67] Staff considers a single, feasible solution for the cost analysis, which requires manufacturers to redesign their respective APBR models to comply with ASTM F3186 – 17, with proposed modifications. Staff assumes that 100 percent of manufacturers will adopt the proposed solution and estimated the cost of the draft final rule under that assumption.

The cost of implementing an APBR fix to address entrapment and strangulation hazards includes the costs manufacturers incur to redesign existing models and produce new designs that comply with ASTM F3186 – 17, as well as the cost of producing the redesigned APBRs.[68] The increased manufacturing cost may then be passed on, at least in part, to wholesalers,

to the nearest hundred thousand. The adjustment is as follows: $7.9M x (278.802/210.228) = $10.477M, which is then rounded to $10.5M.

[66] Additional benefits of the final rule resulting from prevented deaths related to falls other miscellaneous hazard modes are not included and would be supplemental to the reported amounts.

[67] Discounting future estimates to the present allows staff not only to consider the time value of money, but also the opportunity cost of the investment, that is, the value of the best alternative use of funds.

[68] The draft final rule would not require manufacturers to update or replace APBRs manufactured or sold before implementation of the proposed APBR mandatory standards.

retailers, and consumers. The subcategories of costs for implementing a solution to the APBR entrapment and strangulation hazard are detailed below.

Cost on Manufacturers of Redesigning Existing APBR Models and New Designs

Manufacturers incur design costs that include redesigning existing APBR models to comply with the ASTM F3186 – 17 performance requirements, with modifications specified by the final rule. Those costs include:

- Cost of Design Labor
- Cost of Design Production
- Cost of Design Validation
- Cost of Compliance Testing
- Cost of Manufacturing the Redesigned APBR

Although manufacturers would also be required to design all new APBRs with the entrapment and strangulation hazard solution, staff assesses that once existing models have been redesigned with a working solution, new models can adapt to that solution at a minimal cost. Therefore, the additional cost of implementing an entrapment and strangulation hazard solution into future designs is considered negligible, and it is not addressed further in this analysis.

Cost of Design Labor

The cost of labor compensates model designers employed by the manufacturer (or a third-party designer) for the time to produce a blueprint of the redesigned APBR model.

Staff estimated it would require a team of two designers up to 1 month to produce a final blueprint of an APBR model design that complies with the requirements of the draft final rule, or approximately 347 hours.[69] The average compensation rate of a designer is $63.96 per hour for a total cost of $22,536 per redesigned model in 2021 dollars.[70]

Cost of Design Production

The cost of design production covers the materials and labor required to fabricate prototypes of the APBR model.

---

[69] CPSC staff estimated it would take up to two-person months to modify an existing APBR model that does not comply with the requirements of the draft proposed rule, with a maximum of 4 months and a minimum of 1 month. This is 346.67 hours, the average number of hours per month of 173.33 (40 hours a week x 52 weeks a year/12 months) times 2 (two-person months).

[70] As of September 2021, the average total hourly compensation for management, professional, and related workers was estimated at $63.96 (Bureau of Labor Statistics, Table 2 - Employer Costs for Employee Compensation for Civilian Workers by Occupational and Industry Group, https://www.bls.gov/news.release/ecec.t02.htm). The total cost for two-person months as of September 2021 is $22,172.8 (346.67 hours times $63.96). Adjusted by the CPI price index, this estimate increases to $22,535.89 ($22,172.8 x 278.802 / 274.31) as of December 2021 (Bureau of Labor Statistics – Consumer Price Index for All Urban Consumers, Series ID CUUR0000SA0, 1982-84 base period, https://data.bls.gov/cgi-bin/surveymost?cu).

Staff estimated the cost of fabrication of each APBR at $200 per APBR prototype. Staff estimated an average of three APBR prototypes would be required per model redesign, for a total production cost of $600 per model.

Cost of Design Validation

This refers to the costs of conducting validation testing of prototypes to ensure proper functioning of the redesigned APBR model and conformance with preset requirements established by the manufacturer. This is customarily conducted through in-house testing.

Staff estimated 1 day of validation testing would be required per each redesigned APBR model for a total of $21,423 per model.[71]

Cost of Compliance Testing

This expense covers the cost of conducting third-party compliance testing to verify compliance with the requirements of the new APBR mandatory standards.

Staff estimated that, on average, four APBR models would be tested per day, or $5,356 per redesigned model.[72]

Cost of Manufacturing the Redesigned APBR

Manufacturers incur costs to produce redesigned APBRs after implementation of the draft final rule.[73] Manufacturers would likely incur costs to purchase the required materials to fabricate and produce the APBR. However, staff assumes that producing a redesigned APBR would closely match the production cost of existing APBRs. Therefore, the incremental production cost is negligible, and the estimates in this subcategory focus exclusively on the incremental costs of the materials required to produce APBRs compliant with the draft final rule.

Dead Weight Loss

Dead weight loss (DWL) refers to the lost producer and consumer surplus due to reduced quantities of APBRs sold and consumed following price increases resulting from the draft final rule. Producer surplus represents the foregone profit opportunities, meaning the amount that price exceeds marginal cost for those units no longer produced. Consumer surplus represents the foregone utility from consumption, meaning the amount that willingness to pay exceeds price for units no longer consumed.

Staff estimated DWL resulting from the draft final rule to be $68,944 per year, which aggregates to $1.23 million over the 30-year study period under a 3 percent discount rate.

[71] Subject matter expert input was $20,000 in 2020 dollars, which staff inflated to 2021 dollars using the Consumer Product Index (CPI-U).

[72] Subject matter expert input was $5,000 in 2020 dollars, which staff inflated to 2021 dollars using the Consumer Product Index (CPI-U).

[73] The APBR can be fabricated in-house by the manufacturer or by a third-party contractor hired by the manufacturer.

Cost of CPSC Oversight

Staff does not expect the implementation of the final rule to require significant resources by manufacturers of APBRs or additional oversight and compliance monitoring by CPSC staff. Staff reasonably can provide oversight and monitoring of redesigned and new APBR models with existing resources. Therefore, staff assumes the extra costs incurred by the government to provide additional oversight and compliance monitoring to be insignificant, and thus, it is not addressed further in this analysis.

Comparison of Potential Costs and Potential Benefits of APBRs for the Draft Final Rule

The quantifiable annualized benefits, discounted at 3 percent, associated with the proposed requirements to prevent APBR hazards are $200.24 million, $133.49 million, and $66.75 million, under the scenarios of a 75 percent, 50 percent, and 25 percent of achievable benefits, respectively. The annualized cost to industry to comply with the proposed requirements is $2.01 million. The net benefits, the difference in annualized benefits and costs is $198.23 million, $131.48 million, and $64.73 million for these scenarios. Expressed another way, over the 30-year study period, staff found that for each $1 in cost from the draft proposed rule, there is approximately a return of $99.45, $66.30, and $33.15 in societal benefits for each scenario, respectively.

On a per-unit basis, staff estimates the total costs of the proposed rule to be $3.34 per APBR, under a 3 percent discount rate, while the quantifiable benefits of the proposed rule are estimated at $331.78, $221.19, and $110.59 per APBR, for the scenarios of 75 percent, 50 percent, and 25 percent, respectively. This results in net quantifiable benefits of $328.45, $217.85, and $107.26 per APBR, respectively, for each of these scenarios. Expressed differently, over the 30-year study period, staff found that for each $1 in cost of the draft final rule, there is approximately a return of $99.45, $66.30, and $33.15 in benefits, respectively, for each of the three scenarios.

Alternatives to the Draft Final Rule

Staff considered six alternatives to the draft final rule: (1) Do not undertake regulatory action; (2) Conduct only recalls of APBRs, instead of promulgating a final rule; (3) Conduct an educational campaign; (4) Ban APBRs from the market entirely; (5) Require enhanced safety warnings without other requirements; or (6) Implement a proposed rule with a later effective date. Staff does not recommend these alternatives because much of the societal costs associated with APBR use, in the form of fatal and nonfatal injuries, will continue to be incurred by consumers, even if all these alternatives, except for alternative (4), were implemented together. Also, if the Commission promulgated alternative (4), a rule banning APBRs, staff expects benefits, in the form of reduced societal costs, to be substantial. However, the cost to the individual user, and the loss of a product that provides utility to users, may outweigh the benefits. Considering both the quantifiable and unquantifiable costs and benefits, staff concluded that the net benefits of this alternative are likely less than those of the draft final rule. Therefore, staff does not recommend banning APBRs as an alternative action, which, per the definition of APBR, could

effectively remove all consumer products that are: installed or used alongside of a bed; that reduce the risk of falling from the bed; assist the consumer in repositioning in the bed; or assist the consumer in transitioning into or out of the bed from the market.

Significant Issues Raised During the NPR Public Comments

The CPSC received seven comments submitted by the public in response to the preliminary regulatory analysis. Some of these comments described possible economic impacts of the rule, including economic impacts on firms, the utility of the product for consumers, costs associated with the product hazards, and alternative actions that the Commission could take. None of the comments, however, resulted in changes to the regulatory flexibility analysis.

Potential Impact on Small Entities

As required by the Regulatory Flexibility Act, staff identified seven APBR manufacturers that meet the U.S. Small Business Administration (SBA) criteria to be considered small firms. For three of these firms, the estimated cost of the draft final rule exceeds one percent of their annual revenue. Staff assesses the proposed rule would have a significant economic impact on these three firms.

Staff identified one importer of foreign-manufactured APBRs that meets the SBA criteria to be considered a small business. A small importer whose supplier exits the market or does not provide the importer a GCC to the proposed mandatory standard could experience a significant adverse economic impact. For this one small importer, the cost of certification testing would not exceed one percent of annual revenue. Furthermore, given the growing market for APBRs, staff does not anticipate foreign manufacturers exiting the U.S. market. Moreover, staff assumes that foreign manufacturers would provide certifications that small importers could rely on to retain their sales. Therefore, staff assesses the final rule will not have a significant economic impact on APBR importers.

In summary, the draft final rule is likely to have a significant adverse economic impact on three of the seven identified small APBR manufacturers, but it is unlikely to have a significant impact on the one small APBR importer.

Final Rule: Effective Date & Stockpiling

The final rule would establish a mandatory performance standard and test procedure that all APBRs must meet to be sold in the United States. The rule incorporates by reference ASTM F3186 – 17, with modifications, and requires all APBRs sold in the United States to meet the performance requirement specified through the successful completion of a test procedure. Staff's assessments on the effective date and stockpiling provisions based on the available economic data and received comments are provided in the following sections.

Effective Date

The effective date for the draft final rule is 30 days after publication in the *Federal Register*. All APBRs manufactured after that date would be required to comply with the draft final rule. Staff assesses that the APBR industry would be able to comply quickly with the rule because the

modifications needed do not require extensive product redesign. Because the draft final rule incorporates by reference the current voluntary standard, ASTM F3186 – 17, industry has had over five years to prepare to meet the draft final rule's core requirements. Further, as the comments submitted by APBR manufacturer Stander highlight, existing inventory may be available for sale after the effective date (although stockpiling is not permitted, as explained below). Therefore, staff also assesses that firms can comply with the 30-day effective date of the rule without significant disruptions in short-term APBR supply. Finally, staff assesses that the benefits of implementing the rule with a 30-day effective rate, in the form or reduced APBR entrapment fatal and non-fatal injuries, would likely exceed the costs of a temporary disruption in short-term APBR supply, in the event one does occur.

Our assessment is guided by section 9 of the CPSA. Section 9(f)(3) provides "that the rule (including its effective date)" must be "reasonably necessary to eliminate or reduce an unreasonable risk injury associated with such product." Consistent with the judicial review provision of CPSA section 11(c), the determination of reasonable necessity should be supported by substantial evidence. Section 9(g)(1) addresses effective dates in greater detail and requires that the effective date shall not exceed 180 days from the date the rule is promulgated, "unless the Commission finds, for good cause shown, that a later effective date is in the public interest and publishes its reasons for such finding." Similarly, the effective date must not be less than 30 days after promulgation "unless the Commission for good cause shown determines that an earlier effective date is in the public interest."

The CPSC Commissioners determine what effective date is in the public interest, utilizing information and recommendations provided by staff along with other recorded evidence and policy considerations. These factors will be documented in the Commission's final decision. Given the explicit statutory preference for an effective date in the 30-day to 180-day range, the Economics Staff has examined whether there is specific, detailed, and credible evidence that the public interest supports setting an earlier or later effective date. This economic analysis uses the best available evidence (including data collected by CPSC, inputs from received from the public during the notice and comment process, and the professional judgment of CPSC's technical staff) to characterize the impacts to the American economy, including the statutorily required analysis of impacts to small entities. The analysis includes review of various effective date options. Given the statutory direction in the CPSA, staff's economic analysis will recommend an effective date within the 30-day to 180-day range unless (i) there is clear evidence that a shorter or longer period is required to prevent unreasonable burdens, or (ii) a shorter or longer period would ensure a reasonable relationship between expected benefits and costs. This information is intended to assist the Commission's ultimate determination of the appropriate effective date. See, e.g., CPSA § 9(f)(3)(E), (F).

Prohibition on Stockpiling

Given the 30-day window for the effective date, and the familiarity firms already have with the ASTM F3186-17 standard, which should allow firms manufacturing APBRs to comply quickly when the rule becomes effective, the prohibition on stockpiling provision included in the final rule should not have a significant economic impact.

Staff's Conclusion and Recommendations

Staff recommends that the Commission determine that there is an unreasonable risk of injury and death associated with APBRs. Staff concludes that ASTM F3186 – 17 is inadequate to address the hazard unless necessary modifications are made, and despite staff's continued collaboration with ASTM and market outreach efforts, staff has found no evidence of substantial compliance to the voluntary standard, ASTM F3186 – 17.

Staff's analysis of the incident data shows that the majority of APBR victims are considered vulnerable populations such as the elderly and those with medical conditions, and if left unregulated, an average of 32 deaths related to APBR entrapments and strangulations will occur annually between 2024 and 2053.

Staff acknowledges that adopting the draft final rule may result in adverse economic impacts on three of the seven identified small APBR manufacturers. Overall, however, staff's cost-benefit analysis indicates that, even at a pessimistic 25 percent efficacy rate, there will be a substantial reduction in deaths and injuries and society will achieve a monetary benefit of $33.15 for every $1 in costs to ensure all APBRs meet the draft final rule.

Staff recommends that the Commission publish in the *Federal Register* the draft Final Rule under section 9 of the CPSA. Given the industry's familiarity with the ASTM F3186 – 17 voluntary standard and knowledge of ongoing CPSC actions related to APBRs, and the significant net benefits of compliance to the final rule; APBR manufacturers should be able to comply with the rule relatively quickly. Therefore, staff recommends a 30-day effective date for the draft final rule. Also, to avoid stockpiling before the effective date, staff recommends an anti-stockpiling provision that prohibits firms from importing or manufacturing non-compliant products in volumes that exceed 105 percent of the median volume of the last 13 months immediately preceding the month of promulgation of the final rule.

Tab A: Memorandum by The Office of Compliance and Field Operations, Division of Enforcement and Litigation

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

TO: Vineed K. Dayal, Project Manager,
Division of Mechanical Engineering,
Directorate for Laboratory Sciences

DATE: June 28, 2023

THROUGH: Robert Kaye, Director,
Office of Compliance and Field Operations

Jennifer Sultan, Deputy Director,
Office of Compliance and Field Operations

Mary B. Murphy, Division Director,
Division of Enforcement and Litigation

FROM: Caitlin O'Donnell, Trial Attorney,
Division of Enforcement and Litigation

SUBJECT: Adult Portable Bed Rails
Summary of Compliance Actions since June 2020

This memorandum describes enforcement activities involving adult portable bed rails (APBRs) conducted by the Office of Compliance and Field Operations (Compliance) since June 2020.

Industry Letter

In June 2020, Compliance sent letters to 19 APBR manufacturers, urging them to ensure that their products comply with ASTM F3186 – 17; reminding the firms of the deadly entrapment and strangulation hazard; and warning that the CPSC "may regard [non-compliant] products as having a defect which could present a substantial product hazard under section 15(a) of the Consumer Product Safety Act."[1] Four firms responded. Two firms stated that they only manufacture bed rails they considered to be within the FDA's jurisdiction and thus are exempt from ASTM F3186 – 17. One firm promised that it would undertake a review of its products for compliance to the standard, and one firm responded with a general acknowledgment that it had received the letter.

Section 15 Compliance Actions

In September 2020, Compliance began investigating manufacturers of potentially defective APBRs. To identify firms to prioritize for these investigations, we reviewed incident data to

[1] Letter to Manufacturers, Importers, Distributors, and Retailers of Adult Portable Bed Rails and Related Products from Robert S. Kaye, Director, Office of Compliance and Field Operations, https://www.cpsc.gov/s3fs-public/APBR-Compliance-Letter-to-Industry-June22202001.pdf.

pinpoint firms that had at least one known fatal entrapment incident associated with their APBRs, and whose products failed the entrapment performance requirements of ASTM F3186 – 17, according to testing performed by CPSC's Directorate for Laboratory Sciences, Division of Mechanical Engineering (LSM).

In addition to these initial investigations, Compliance subsequently pursued recalls with additional manufacturers of APBRs. In total, as described below, since June 2020 CPSC has issued two unilateral notices and announced six voluntary recalls of APBRs.

In April 2021, CPSC warned consumers to stop using three models of APBRs manufactured by Bed Handles, Inc. (Bed Handles), a company that is out of business.[2] Compliance determined that the products posed an entrapment hazard and risk of asphyxia to users, who could become entrapped within the rails of the products, or between the rails and mattress. The three product models failed to comply with the performance requirements of ASTM F3186 – 17.

Similar versions of the Bed Handles bed rails were recalled in May 2014,[3] because the handles could shift out of place, creating a hazardous gap between the bed rail and mattress. At that time, consumers who participated in the recall were provided with retention straps that were not permanently attached. Subsequent analysis by technical staff revealed that consumers may not use retention straps if they are not permanently attached. Consequently, the ASTM standard, published in 2017, requires that retention straps be removable only with the use of a tool. Accordingly, upon reevaluating these products' retention systems, LSM concluded that the previously approved remedy was insufficient to protect consumers from entrapment. The 2021 press release warns consumers about the risks associated with all versions of these models and requests that consumers discard them.

Bed Handles distributed approximately 193,000 products, including those previously recalled. CPSC is aware of four entrapment deaths involving bed rails distributed by Bed Handles.

On December 6, 2021, CPSC and Medical Depot, Inc., d/b/a Drive DeVilbiss Healthcare (Drive), announced a voluntary recall of four models of APBRs, based on the products' presenting an entrapment hazard and risk of asphyxia.[4] Drive imported and distributed approximately 496,100 units of the recalled bed rails from October 2007 to June 2021. Two entrapment deaths were associated with two different models: one in California in 2011, and one in Canada in 2015. As a remedy, Drive is providing consumers with a full refund.

On December 22, 2021, CPSC announced the voluntary recalls of APBRs manufactured by Compass Health Brands (Compass) and Essential Medical Supply, Inc. (Essential). Compass

---

[2] PR #21-122, https://www.cpsc.gov/Newsroom/News-Releases/2021/CPSC-Warns-Consumers-to-Stop-Use-of-Three-Models-of-Adult-Portable-Bed-Rails-Manufactured-by-Bed-Handles-Inc-Due-to-Entrapment-Asphyxia-Hazard.

[3] PR #14-185. The recall was re-announced twice: first on September 17, 2015 (PR #15-245), due to a low response rate, and again on October 7, 2015 (PR #16-005), after a fourth entrapment death was reported.

[4] PR #22-025, https://www.cpsc.gov/Recalls/2022/Drive-DeVilbiss-Healthcare-Recalls-Adult-Portable-Bed-Rails-After-Two-Deaths-Entrapment-and-Asphyxiation-Hazards.

recalled two models of Carex-brand bed rails that presented an entrapment hazard and risk of asphyxia.[5] Compass distributed approximately 104,900 units of the recalled products from November 2012 to May 2021. Three entrapment deaths were associated with one of the models. They occurred between April 2014 and June 2020. As a remedy, consumers received either a CPSC-approved repair kit or a refund, depending on the model.

Essential recalled four models of bed rails due to their presenting an entrapment hazard and risk of asphyxia.[6] Essential distributed approximately 272,000 units of the bed rails from October 2006 to March 2021. One entrapment death was reported that occurred in December 2012. Essential is providing a refund to consumers who own bed rails sold or imported on or after November 1, 2015. The refunds are pro-rated based on the age of the bed rail. The news release warns consumers with older bed rails to stop use and dispose of them.

On June 2, 2022, CPSC issued a unilateral notice warning consumers to stop use and dispose of 10 models of APBRs manufactured and sold by Mobility Transfer Systems, Inc. (MTS), from 1992 to 2021, and by Metal Tubing USA, Inc. (MTU), in 2021 and 2022.[7] MTU purchased the majority of the assets of MTS, including its brand name and product line, on March 29, 2021. Compliance determined that these models presented an entrapment hazard and risk of asphyxia. Three entrapment deaths involving one model of the bed rails occurred between 2006 and 2013. In total, approximately 285,000 units were manufactured, distributed, and sold by MTS and MTU. MTS is no longer in business, and neither company has agreed to conduct a recall with a remedy for consumers.

On December 22, 2022, CPSC announced the voluntary recall of two models of APBRs manufactured by Nova Ortho-Med, Inc. (Nova), due to their presenting an entrapment hazard and risk of asphyxia.[8] Nova distributed approximately 20,000 units of the recalled bed rails from January 2019 through November 2022. Nova is providing a repair or replacement remedy to consumers, depending on the model.

On February 23, 2023, Platinum Health, LLC (Platinum), recalled three models of LumaRail-brand APBRs. Platinum distributed approximately 53,000 units of the bed rails from July 2015 through December 2022.[9] One entrapment death occurred in Pennsylvania in October 2021. As

[5] PR #22-040, https://www.cpsc.gov/Recalls/2022/Compass-Health-Brands-Recalls-Carex-Adult-Portable-Bed-Rails-After-Three-Deaths- Entrapment-and-Asphyxiation-Hazards.

[6] PR #22-039, https://www.cpsc.gov/Recalls/2022/Essential-Medical-Supply-Recalls-Adult-Portable-Bed-Rails-Due-to-Entrapment-and-Asphyxia-Hazard-One-Death-Reported.

[7] PR #22-148, https://www.cpsc.gov/Newsroom/News-Releases/2022/CPSC-Urges-Consumers-to-Immediately-Stop-Use-of-Mobility-Transfer-Systems-Adult-Portable-Bed-Rails-Due-to-Entrapment-and-Asphyxia-Hazard-Three-Deaths-Reported.

[8] PR #23-081, https://www.cpsc.gov/Recalls/2023/Nova-Medical-Products-Recalls-Adult-Bed-Rails-Due-to-Serious-Entrapment-and-Asphyxia-Hazards.

[9] PR #23-136, https://www.cpsc.gov/Recalls/2023/Platinum-Health-Recalls-LumaRail-Adult-Portable-Bed-Rails-Due-to-Serious-Entrapment-and-Asphyxia-Hazard-One-Death-Reported.

a remedy, Platinum is offering a free repair kit to most consumers; consumers who use one of the models on a twin bed will receive a replacement redesigned to properly fit twin beds.

On March 9, 2023, CPSC announced the voluntary recall of two models of Vaunn Medical Bed Assist Rail APBRs that present an entrapment hazard and risk of asphyxia.[10] Einstein Associates, LLC, sold approximately 102,000 units via its website, BeyondMedShop.com, and via its BeyondMedShop storefront on e-commerce platforms, from December 2018 through December 2022. As a remedy, Einstein Associates is offering a repair kit to consumers.

Compliance continues to investigate reports of entrapment involving APBRs on an ongoing basis.

[10] PR #23-151, https://www.cpsc.gov/Recalls/2023/BeyondMedShop-Recalls-Vaunn-Medical-Adult-Bed-Rails-Due-to-Serious-Entrapment-and-Asphyxia-Hazards.

Tab B: Proposed Changes to ASTM F3186-17 for the Final Rule

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

TO: Vineed K. Dayal, Project Manager,
Division of Mechanical Engineering,
Directorate for Laboratory Sciences

DATE: June 28, 2023

THROUGH: CPSC Adult Portable Bed Rail Project Team

FROM: Adam Howie, Mechanical Engineer,
Division of Mechanical Engineering,
Directorate for Laboratory Sciences

SUBJECT: Proposed Changes to ASTM F3186-17 for the Final Rule

---

Introduction

Staff has developed modifications to ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*, for the final rule in order to adequately address known product hazards associated with APBRs. The Commission solicited comments on *Notice of Proposed Rulemaking for Adult Portable Bed Rails* published in the *Federal Register*. Staff reviewed the seven comments and recommend changes to the proposed based on commenters' suggestions.

Requirements for Adult Portable Bed Rails

Staff recommends several changes to the language in the proposed rule based on the comments received. The recommended changes are intended to clarify certain sections, and improve safety, as follows:

- Adding new definitions to ensure consistency throughout the rule.
- Improving requirements for manufacturers to inform the consumer of the range of mattress thicknesses to ensure safe use of the product and to provide testers with guidance for selecting the correct mattress thickness during the test setup.
- Updating the requirements for entrapment testing to be consistent with known hazards.

The staff recommended changes would be included in §1270.2 (b), and are described below by section. Staff's rationale is provided for all recommended changes to the standard. This list contains all of staff's recommended changes for the draft final rule based on the comments received. This section provides staff's recommended language for the final rule.

(1) In addition to complying with the definitions in section 3.1 of ASTM F3186 – 17, comply with the following:

(i) *3.1.5 Entrapment Zone*, n- An area, gap, or opening that can potentially capture or restrain a person's body part. Hazardous openings may not always be visible prior to testing.

Rationale: ASTM F3186 – 17 does not formally define what an entrapment zone is. This global definition for the final rule will provide this necessary information and will lead to more consistent interpretations for what an entrapment zone is and where they can be found for testing.

(ii) *3.1.7 Initial Assembly*, n— the first assembly of the product components after purchase, and prior to installing on the bed.

(iii) *3.1.8 Initial Installation*, n— the first installation of the product onto a bed or mattress.

Rationale: These new definitions are intended to differentiate between "assembly" and "installation" to clarify when the requirements in section 6.1.3 and 9.2.7 apply (see below).

(iv) *3.1.9 Installation Component*, n— component(s) of the bed rail that is/are specifically designed to attach the bed rail to the bed. These components are typically located under the mattress when in the manufacturer's recommended use position.

Rationale: This term was previously used throughout the standard but was not defined. This new definition is required to establish the location of the required warning label from section 9.2.7 (see below). This definition is adopted from the Children's Portable Bed Rail standard (16 C.F.R. § 1224).

(2) Instead of complying with section 6.1.3 of ASTM F3186 – 17, comply with the following:

(i) Under section 6.1.3, permanently attached retention system components shall not be able to be removed without the use of a tool after initial assembly.

Rationale: Making the retention system permanent during product assembly ensures that retention system integrity is maintained, even if the product is reinstalled after initial assembly. Retention systems are a critical component for reducing known product hazards. Removable retention systems are known to lead to entrapment and strangulation hazards. The retention system should remain attached to the product and should not be compromised after initial assembly and between uninstallation, and reinstallation of the product.

(3) In addition to complying with section 6.2.1 of ASTM F3186 – 17, comply with the following:

(i) Under section 6.2.1, the test personnel shall choose a mattress and product setting configuration that results in the most severe condition per test requirement (see 7.1.3).

Rationale: Defining a range of recommended mattress thicknesses provides consumers with necessary information for the safe use of the product. Similarly, products may come with many types of adjustable settings and consumers may incorrectly assume all settings are safe for any

given mattress. Selecting the mattress and product setting which provide the most severe conditions for each test will ensure that all hazards are adequately addressed. This requirement is supplemental to the misassembly-related requirements in section 6.5. Modifications to the originally proposed language were made based on a comment received in response to the NPR. The commenter indicated that the original proposed language seemed to create an alternative requirement for manufacturers who do not provide a recommended thickness range, as required by section 9.1.1.3 of the voluntary standard.

(4) Instead of complying with section 6.3.3 of ASTM F3186 – 17, comply with the following:

(i) Under section 6.3.3, *Zone 3*— When tested in accordance with section 8.4.5, the horizontal centerline on the face of the 4.7 in (120 mm) end of the test probe (see 7.2) shall be above the highest point of the uncompressed mattress.

Rationale: The Zone 3 entrapment performance requirement in section 6.3.3 is redundant due to the failure criteria described in the associated test method, section 8.4.5.4. The failure criteria described in this test method is the intended requirement and is more consistent with the FDA guidance document referenced in the standard. This is also the more safety protective interpretation. If not corrected, testers may mistakenly choose to follow the incorrect pass/fail criteria. Figures are included to assist testers in visualizing the test criteria.

(5) Instead of complying with section 6.4.1 of ASTM F3186 – 17, comply with the following:

(i) Under section 6.4.1, holes or slots that extend entirely through a wall section of any rigid material less than 0.375 in (9.53 mm) thick and admit a 0.210 in (5.33 mm) diameter rod shall also admit a 0.375 in (9.53 mm) diameter rod. Holes or slots that are between 0.210 in (5.33 mm) and 0.375 in (9.53 mm) and have a wall thickness less than 0.375 in (9.53 mm) but are limited in depth to 0.375 in (9.53 mm) maximum by another rigid surface shall be permissible (see Fig. 2).

Rationale: The measurement references in 6.4.1 were not consistent or accurate with themselves or the referenced Figure 2. The proposed changes to this section fixes those issues and harmonize the requirements with other established ASTM standards that have similar requirements, including F2085 (Children's Portable Bed Rails).

(6) Instead of complying with section 6.5.1 of ASTM F3186 – 17, comply with the following:

(i) Under section 6.5.1, any structural components and retention system components of a product covered by this specification that require consumer assembly or adjustment, or components that may be removed by the consumer without the use of a tool, shall not be able to be misassembled when evaluated to 6.5.2.

Rationale: Editorial change to clarify that disassembly with the use of a tool is not considered to be "misassembly" under section 6.5.

(7) Instead of complying with section 6.5.2 of ASTM F3186 – 17, comply with the following:

(ii) Under section 6.5.2, Determining Misassembled Product: A product covered by this specification shall be considered misassembled if it appears to be functional under any condition and it does not meet the requirements of 6.1–6.4.

Rationale: Editorial change, misspelling.

(8) In addition to complying with section 7.1 of ASTM F3186 – 17, comply with the following:

(i) Under section 7.1.3, mattress thickness ranges used for testing shall be up to 1.5 in (38 mm) larger or smaller than the range specified by the manufacturer. The test personnel shall choose a mattress and product setting configuration that provide the most severe condition for each test requirement in the standard.

Rationale: Consumers are not necessarily expected to measure mattress thickness, nor are they expected to purchase a new mattress for proper compatibility. Additionally, consumers are likely to follow general descriptions of their mattresses which may vary from the actual specifications. Adding this additional range will increase safety by accounting for foreseeable differences between nominal and actual mattress thicknesses, as well as consumer selection which may deviate from manufacturer recommendations. Modifications to the originally proposed language were made based on a comment received in response to the NPR. The commenter indicated that the original proposed language seemed to create an alternative requirement for manufacturers that do not provide a recommended thickness range, as required by section 9.1.1.3 of the voluntary standard.

(ii) Note: The technology and consumer preferences for bedding are highly variable and continuously changing. Therefore, they cannot be reasonably accounted for within this standard. Test facilities and personnel should consider current bedding trends and all types of mattresses that may foreseeably be used with the product when making a test mattress selection.

Rationale: Mattress type is a known variable for testing that is continuously changing based on bedding preferences and technology. Manufacturers and testers should be aware of the types of mattresses consumers may be using with these products in practice and test accordingly.

(9) Instead of complying with section 7.2 of ASTM F3186 – 17, comply with the following:

(i) Under section 7.2, *Entrapment Test Probe*—The test probe shall be as described in the FDA Guidance Document, "*Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment*," which can be found at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment. The test probe can be independently manufactured per the dimensional constraints in the guidance document or purchased from Bionix, 5154 Enterprise Blvd., Toledo, OH 43612, 800-551-7096, *www.bionix.com.* Videos illustrating use of the test probe are available at: *www.youtube.com/c/BionixLLC/search.*

Rationale: Editorial change, the previous hyperlink and business contact information was out of date. The updated company information is as follows: Bionix, 5154 Enterprise Blvd, Toledo, OH 43612, 800-551-7096, https://bionix.com. Videos illustrating use of the test probe are available at: https://www.youtube.com/c/BionixLLC/search?query=Bed%20Rail.

(10) Instead of complying with NOTE 1 in section 8.4 of ASTM F3186 – 17, comply with the following:

(i) Note: The tests described in this section are similar to those described in the referenced FDA Guidance Document.

Rationale: Editorial change. Although the FDA guidance document is the source of the entrapment test methodologies in the voluntary standard, there are several differences in this proposed rule in favor of safety and to make the tests more applicable to the consumer product versions of bed rails.

(11) Instead of complying with section 8.4.3.4 of ASTM F3186 – 17, comply with the following:

(i) Under section 8.4.3.4, If the test probe does not pull through freely, attach the force gauge and exert a 22.5 lbf (100 N) pulling force to the 2.4 in (60 mm) cylindrical end of the entrapment test tool probe in the direction most likely to lead to failure of the requirement. If the 4.7 in (120 mm) end of the cone does not enter any of the openings, this space passes the test. If the 4.7 in (120 mm) end of the test probe cone does enter any of the openings, this space fails the test.

Rationale: In response to the NPR, a commenter proposed alternative entrapment testing methods and interpretations that limit the orientation of the test probe and application of force in a way that would not represent known entrapment hazards. The proposed language has been modified to remove restrictions on how the probe and force should be applied to better represent the known hazards. The intent of this test is to address entrapment hazards associated with bed rails and head entrapment in Zone 2 by ensuring the test probe cannot pass through any openings in the entrapment zone. This criterion is based on the FDA guidance document, which includes a dimension of 120 mm (4.75 in), encompassing the 5th percentile female head breadth, which represents the smallest and most at-risk consumers who will foreseeably use APBRs. This dimension is represented by the 4.7 in portion of the test probe and should be applied in any orientation in which the head may be entrapped.

(12) Instead of complying with section 8.4.4.3 of ASTM F3186 – 17, comply with the following:

(i) Under section 8.4.4.3, Insert the 2.4 in (60 mm) end of the cone into the opening at the angle most likely to allow it to pass through. Insert the cone into the opening until it is in full contact with the product. The mattress shall only be compressed by the weight of the cone.

Rationale: In response to the NPR, a commenter proposed alternative entrapment testing methods and interpretations that limit the orientation of the test probe and application of force in

a way that would not represent known entrapment hazards. The proposed language has been modified to remove restrictions on how the probe and force should be applied to better represent the known hazards. The intent of this test is to address entrapment hazards associated with bed rails and head entrapment in Zone 2 by ensuring the test probe cannot pass through any openings in the entrapment zone. This criterion is based on the FDA guidance document, which includes a dimension of 120 mm (4.75 in), encompassing the 5th percentile female head breadth, which represents the smallest and most at-risk consumers who will foreseeably use APBRs. This dimension is represented by the 4.7 in portion of the test probe, which should be applied in any orientation in which the head may be entrapped.

(13) Instead of complying with section 8.4.4.4 of ASTM F3186 – 17, comply with the following:

(i) Under section 8.4.4.4, if the test probe does not pull through freely use the force gauge to exert a 22.5 lbf (100 N) pulling force to the 2.4 in (60 mm) cylindrical end of the cone in the direction most likely to lead to failure of the requirement.

Rationale: In response to the NPR, a commenter proposed alternative entrapment testing methods and interpretations that limit the orientation of the test probe and application of force in a way that would not represent known entrapment hazards. The language has been modified to remove restrictions on how the probe and force should be applied to better represent the known hazards. The intent of this test is to determine if both the 2.4 in and 4.7 in portions of the test probe can enter or pass through the Zone 2 opening under the required force. This would mean that a body part can be entrapped, and a hazard is present. Removing restrictions on how the force should be applied better represents the known hazards. Applying the force perpendicular to the 2.4 in face of the probe may not always emulate the known hazard of head or limb entrapment. Applying the pull force in the direction most likely to lead to failure of the requirement represents these known hazards better when compared to a pull force applied perpendicular to the face of the rail.

(14) In addition to complying with section 8.4.4 of ASTM F3186 – 17, comply with the following:

(i) Under section 8.4.4.5, if an entrapment zone greater than 4.7 in exists along the bottom of the rail, that section must meet the Zone 2 requirements regardless of the number or location of the supports. Repeat testing described in sections 8.4.4.3 and 8.4.4.4 for all applicable entrapment zones. Figure 1 below shows a general example of areas subject to Zone 2 requirements.

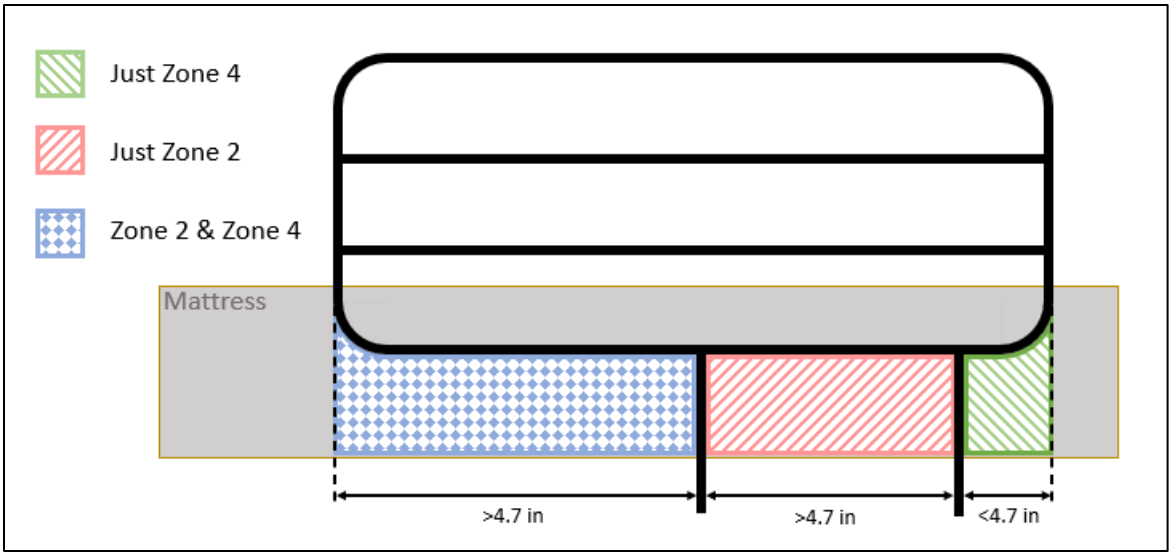


Figure 1: General example of areas subject to Zone 2 requirements.

Rationale: In response to the NPR, a commenter brought up concerns about the location of zone 2 on bed rails with multiple supports. Zone 2 testing is meant to address head-first entry under the rail into any opening between the mattress compressed by the weight of a consumer's head and a section of the bedrail. Bed rails that have overhanging elements longer than 4.7 inches can allow the passage of the head in a manner consistent with identified Zone 2 entrapment hazards regardless of the number or location of vertical support rails. 4.7 inches is the diameter of the test probe and encompasses the 5th percentile female head breadth. This language and figure clarify all areas that should be included in Zone 2 testing.

(15) Instead of complying with section 8.4.5.4 of ASTM F3186 – 17, comply with the following:

(i) Under section 8.4.5.4, turn the cone until the line on the face of the 4.7 in (120 mm) end is horizontal and let the cone sink into the space by its own weight.

(A) If the line on the face of the 4.7 in (120 mm) end of the cone is above the highest point of the uncompressed mattress, as shown in Figure 2a, the space passes the test.

(B) If the line on the face of the 4.7 in (120 mm) end of the cone is at or below the highest point of the uncompressed mattress, as shown in Figure 2b, the space fails the test.

Figure 2: Zone 3 test: (a) **Pass**, (b) **Fail**

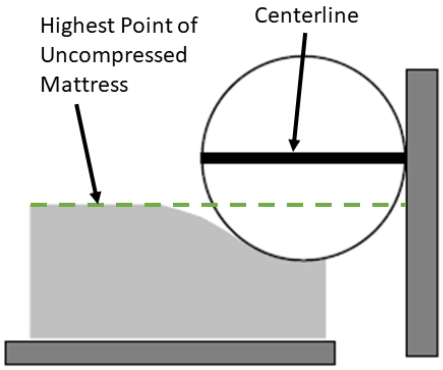


Figure 2a: Zone 3 **Pass** Criteria (Centerline **above** highest point of uncompressed mattress)

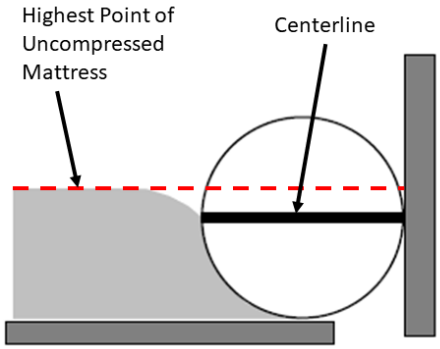


Figure 2b: Zone 3 **Fail** Criteria (Centerline **below** highest point of uncompressed mattress)

Rationale: The Zone 3 entrapment performance requirement in section 6.3.3 is redundant due to the failure criteria described in the associated test method, section 8.4.5.4. The failure criteria described in the test method is the intended requirement, which would also be more consistent with the FDA guidance document referenced in the standard and is the interpretation in favor of safety. In addition, the Figures are included to assist testers in visualizing the test criteria.

(16) In addition to complying with section 8.6.3 of ASTM F3186 – 17, comply with the following:

(i) Note: The "free end" is defined as the location on the retention system that is designed to produce a counter force; it may be a single distinct point or a location on a loop.

Rationale: Section 8.6.3 requires a 50 lbf force to be applied to the "free end" of the retention system without defining the term. This note will clarify the test method for test operators, improve repeatability, and reduce the potential for test errors. Adopting this note would make it "Note 4" and make the current Note 2, "Note 5."

(17) Instead of complying to section 9.1.1.3 of ASTM F3186 – 17, comply with the following:

(i) Under section 9.1.1.3, that the product is to be used only with the type and size of mattress and bed, including the range of thickness of mattresses, specified by the manufacturer of the product. If beds with head or footboards are allowed, the distance between the head or footboard and the placement of the product shall be indicated to be >12.5 in (318 mm).

Rationale: This recommended change addresses an inconsistency between 9.1.1.3, which states that products may be installed <2.4 in or >12.5 in away from head or footboards, and 9.2.6, which states that products must be installed at least 12.5 in from headboards or footboards. The ASTM F15.70 revision task group has reviewed and agreed to these changes.

(18) Instead of complying with section 9.2.5 of ASTM F3186 – 17, comply with the following:

(i) Under section 9.2.5, each product's retail package and instructions shall include the following warning statements:

⚠WARNING
ENTRAPMENT, STRANGULATION, SUFFOCATION AND FALL HAZARDS
Gaps in and around this product can entrap and kill. People with Alzheimer's disease or dementia, or those who are sedated, confused, or frail are at increased risk of entrapment and strangulation. People attempting to climb over this product are at increased risk of injury or death from falls. Always make sure this product is properly secured to bed. If product can move away from bed or mattress, it can lead to entrapment and death.

Rationale: This change is editorial and aligns the language with similar language used in Section 9.2.6.

(19) Instead of complying to section 9.2.7 of ASTM F3186 – 17, comply with the following:

(i) Under section 9.2.7, at least one installation component of the product must be labeled with the following entrapment warning:

⚠WARNING – ENTRAPMENT HAZARD
NEVER use product without properly securing it to bed. Incorrect installation can allow product to move away from mattress, bed frame and/or head or foot boards, which can lead to entrapment and death.

Rationale: The warning, as used in 16 CFR § 1224, is intended to draw attention to the installation component and to encourage its use. During the development of ASTM F3186, CPSC staff recommended that a similar requirement be added, and a draft of the voluntary standard included such a requirement. However, before publication of the voluntary standard, the requirement for this warning to be on an installation component was changed to say that it must be located on a "conspicuous component." The installation component is commonly located under the mattress during use, and therefore, the warning would not be "conspicuous" when in the manufacturer's recommended use position. Requiring the warning to be on a "conspicuous component" most likely would not permit the warning to be placed on an installation component. The recommended language would return the requirement to its original intent, drawing attention to the installation component. The warning required by Section 9.2.6, which also discusses entrapment hazards and keeping the product tight against the mattress, is required to be placed on an installation component.

(20) Instead of complying with section 11.1.1.3 of ASTM F3186 – 17, comply with the following:

(i) Under section 11.1.1.3, in addition to contacting the manufacturer directly, consumers should report problems to the CPSC at its website SaferProducts.gov or call 1-800-638-2772, or to the FDA at 1-800-332-1088.

Rationale: Editorial change, grammatical revision.

Tab C: Final Regulatory Analysis Memorandum by the Directorate for Economic Analysis

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

TO: Vineed K. Dayal, Project Manager,
Division of Mechanical Engineering,
Directorate for Laboratory Sciences

DATE: June 28, 2023

THROUGH: Alex Moscoso, Associate Executive Director,
Directorate for Economic Analysis

FROM: Rodney R. Row, Economist,
Directorate for Economic Analysis

SUBJECT: Adult Portable Bed Rail Final Regulatory Analysis

Executive Summary

The U.S. Consumer Product Safety Commission (CPSC, or the Commission) is considering a draft final rule for Adult Portable Bedrails (APBR) to address the risk of entrapment and other hazards associated with these products. CPSC staff assesses that the voluntary standard, ASTM International (ASTM) F3186-17, *Standard Specification for Adult Portable Bed Rails and Related Products,* with modifications, would largely address known APBR hazards. However, CPSC compliance testing conducted in 2018-2019 and 2021, indicates there is not substantial industry compliance with ASTM F3186 – 17. CPSC staff concludes that a mandatory rule that incorporates by reference ASTM F3186 – 17, with some modifications, can significantly reduce the risks of entrapment and other APBR hazards.

Since the Notice of Public Rulemaking (NPR) for APBRs was published in the *Federal Register* on November 9, 2022, staff has not identified any meaningful changes in the APBR market, or in the data used in the preliminary analysis of benefits and costs. The CPSC received seven comments regarding the NPR for APBRs. Though some of the comments described possible economic impacts of the rule, none required changes to the regulatory analysis. Therefore, staff incorporates by reference the NPR regulatory analysis, which may be found at https://www.federalregister.gov/documents/2022/11/09/2022-22692/safety-standard-for-adult-portable-bed-rails, into this memorandum. A summary of significant issues raised by comments and staff's assessment of these issues appear in the Staff Briefing Memorandum; those with possible economic impacts are also discussed in the Appendix to this tab. The remainder of this Executive Summary presents the key findings of the regulatory analysis.

The market for APBRs is expected to grow at an average rate of 2.01 percent per year between 2024 and 2053 as an aging U.S. population seeks to avoid the increasing costs of institutional medical care. If left unregulated, and assuming the rates of incidents per million APBRs stay constant, this growth in the industry would lead to an average of 32 deaths per year. At a value

of a statistical life (VSL) of $10.5 million (2021 dollars), the annualized present value[1] of the potential benefits is $298.11 million.

Staff did not include injuries in its benefit-cost assessment because many incident reports involving injuries did not have sufficient information to determine whether the injury would fall under the scope of the rule.[2] However, in the NPR sensitivity analysis, Section VI. A. 3, staff did quantify and monetize the injuries using the CPSC's Injury Cost Model and, by making assumptions about the potential share of incidents that would fall under the scope of the rule, illustrate a potential upper limit for the benefits of the rule.

The requirements of the rule are expected to address 92 percent of deaths caused by entrapment and strangulation. However, the effectiveness of the draft final rule depends, to some extent, on consumers installing the product correctly. The draft final rule provides significant improvements designed to help consumers; however, there may still be some injuries and deaths resulting from improper installation of APBRs or installation on mattresses that, due to their thickness, are inappropriate for the product. CPSC staff cannot provide a precise measure of effectiveness of the draft final rule. Therefore, to assess potential benefits, staff considers three scenarios with three different levels of effectiveness: 75 percent, 50 percent, and 25 percent of potential benefits. At these rates, CPSC staff estimates the annualized benefits of the rule to be $200.24 million, $133.49 million, and $66.75 million, respectively. CPSC staff estimated annualized costs associated with the draft final rule to be $2.0 million. This results in annualized net benefits of $198.23 million, $131.48 million, and $64.73 million, for each level of effectiveness respectively.

CPSC staff's research and analysis demonstrate that the requirements of the rule will decrease APBR deaths by reducing the occurrence of entrapment and other hazards. CPSC staff also concludes that the recommended requirements are technologically feasible, and that the potential benefits of the rule substantially exceed the rule's costs. For these reasons, CPSC staff recommends that the Commission publish the APBR final rule submitted with this briefing package.

1. Introduction

The CPSC is considering issuing a final rule that establishes a mandatory performance requirement and test procedure to reduce the risk of entrapment and other hazards associated with the use of APBRs. Staff's draft final rule would incorporate by reference ASTM F3186-17, with modifications, and require all APBRs sold in the United States and manufactured after the effective date to comply with the standard's performance and testing requirements.

[1] The cost and benefit amounts discussed in these paragraphs are based on the present value of future costs and benefits discounted to the present at a 3 percent discount rate. Amounts per year are annual equivalents, also estimated using a 3 percent rate. Costs and benefits are presented in 2021 dollars. Some estimates may not exactly add up, due to rounding.

[2] Staff was unable to determine if some injuries were caused by an APBR or some other type of bed rail. Also, staff was unable to determine specific causes of injuries in some reports.

1.1. Draft Final Rule

The draft final rule would establish a mandatory performance standard and test procedure that all APBRs must meet to be sold in the United States. The draft rule would incorporate by reference ASTM F3186, with modifications, and require all APBRs sold in the United States to meet the performance requirement specified through the successful completion of a test procedure (Howie, 2023, (TAB B)).

1.1.1 Effective Date

The effective date for this draft final rule would be 30 days after publication in the *Federal Register*. All APBRs manufactured after that date would be required to comply with the draft final rule. Firms will be able to continue to sell products manufactured before the effective date. Staff assesses that the APBR industry would be able to comply quickly with the rule because the modifications needed do not require extensive product redesign. Further, because the draft final rule incorporates by reference the current voluntary standard, ASTM F3186 – 17, industry has had over five years to prepare to meet the draft final rule's core requirements. Therefore, staff also assesses that firms can comply without significant disruptions in short-term APBR supply. In addition, staff notes that the only commenter expressing concern about a 30 day effective date, APBR firm Stander, stated that for some of its models it has at least a year's worth of existing stock that is compliant with the existing ASTM standard, giving it more than enough time to manufacture APBRs compliant with the draft final rule before exhausting its existing inventory. Finally, staff assesses that the benefits of implementing the rule with a 30-day effective rate, in the form or reduced APBR entrapment fatal and non-fatal injuries, would exceed the costs of a temporary disruption in short-term APBR supply, in the unlikely event one does occur.

Staff's assessment is guided by section 9 of the CPSA. Section 9(f)(3) provides "that the rule (including its effective date)" must be "reasonably necessary to eliminate or reduce an unreasonable risk injury associated with such product." Section 9(g)(1) addresses effective dates in greater detail and requires that the effective date shall not exceed 180 days from the date the rule is promulgated, "unless the Commission finds, for good cause shown, that a later effective date is in the public interest and publishes its reasons for such finding." Similarly, the effective date must not be less than 30 days after promulgation "unless the Commission for good cause shown determines that an earlier effective date is in the public interest."

The CPSC Commissioners determine what effective date is in the public interest, utilizing information and recommendations provided by staff along with other recorded evidence and policy considerations. These factors will be documented in the Commission's final decision. Given the explicit statutory preference for an effective date in the 30-day to 180-day range, the Economics Staff has examined whether there is specific, detailed, and credible evidence that the public interest supports setting an earlier or later effective date. This economic analysis uses the best available evidence (including data collected by CPSC, inputs from received from the public during the notice and comment process, and the professional judgment of CPSC's

technical staff) to characterize the impacts to the American economy, including the statutorily required analysis of impacts to small entities. The analysis includes review of various effective date options. Given the statutory direction in the CPSA, staff's economic analysis will recommend an effective date within the 30-day to 180-day range unless (i) there is clear evidence that a shorter or longer period is required to prevent unreasonable burdens, or (ii) a shorter or longer period would ensure a reasonable relationship between expected benefits and costs. This information is intended to assist the Commission's ultimate determination of the appropriate effective date. See, e.g., CPSA § 9(f)(3)(E), (F).

1.1.2 Stockpiling

The familiarity firms already have with ASTM F3186-17 should allow them to comply with the draft final rule within the 30-day effective date. However, to avoid potential stockpiling, staff recommends a provision on stockpiling that prohibits firms from importing or manufacturing non-compliant products in volumes that exceed 105 percent of the median volume of the last 13 months immediately preceding the month of publication of the draft final rule.

1.2. Final Regulatory Analysis

Section 9(f)(2) of the Consumer Product Safety Act (CPSA) requires that the Commission publish a "final regulatory analysis" in the *Federal Register* containing:

- A description of the potential benefits and potential costs of the rule, including costs and benefits that cannot be quantified in monetary terms, and the identification of those likely to receive the benefits and bear the costs.
- A description of any alternatives to the final rule which were considered by the Commission, together with a summary description of their potential benefits and costs and a brief explanation of the reasons why these alternatives were not chosen. Regulatory alternatives are discussed in Section 7 of this Tab.
- A summary of any significant issues raised by the comments submitted during the public comment period in response to the preliminary regulatory analysis, and a summary of the assessment by the Commission of such issues. A summary of significant issues raised by comments and the staff's assessment of these issues appears in the Briefing Memo; those with possible economic impact are also discussed in the Appendix to this Tab.

2. Description of the Product and Market

APBRs refer to a range of adjacent type bed rails, grab bars, assistive bars, transfer aids, canes, or rails intended by the manufacturer to be installed on, against, or adjacent to an adult bed. The product may vary in length (for example, full, half, or partial rails, grab bar or handle or transfer post or pole) and is intended by the manufacturer to aid the bed occupant in moving on the bed surface, in entering or exiting the bed, to minimize the possibility of falling out of bed, or for other similar purposes. This includes similar products that are likely to be used for these

purposes, even if not explicitly stated by the manufacturer. However, APBRs do not include all products that might be used for this function, for example, a chair. Nor does this product category include bedrails that are integral to, or accessories of, hospital beds. An "adjacent type bed rail" is defined as a portable bed rail or related product in which the guard portion (portion that an adult would contact when rolling toward the mattress edge) is essentially a vertical plane or pole(s) that is(are) positioned against the side of the mattress. (ASTM, 2017).

Section II of the preamble of the NPR provides a description of the APBR market, including its size, prices, revenues, historic and projected growth, and compliance with the voluntary standard, ASTM F3186 – 17.

3. Final Regulatory Analysis: Benefits Assessment

Staff conducted the final regulatory analysis from a societal perspective that considers significant costs and health outcomes (Gold et al., 1996; Haddix, Teutsch, and Corso, 2003; Neumann et al., 2016). Staff captured the expected reduction in societal costs by estimating the number of deaths from entrapment and strangulation that would be prevented by the rule. The Directorate for Epidemiology (EP) retrieved casualties reported through the National Electronic Injury Surveillance System (NEISS), a national probability sample of U.S. hospital emergency departments (ED), and the Consumer Product Safety Risk Management System (CPSRMS), a database of consumer incident reports. Staff then forecast the number of expected deaths for a 30-year study period and converted the value of prevented casualties into monetary terms using the Value per Statistical Life (VSL) for deaths.

Staff used a 30-year study period to assess the benefits of the rule. Staff chose to begin its analysis in the first full calendar following the expected publication of the rule; this results in a study period of 2024 through 2053. A 30-year period allows for several cycles of useful life for APBRs and ensures the benefits assessment accounts for any latent, long-term, and refresh effects from the rule. Staff then converted the aggregate benefits over the 30-year study period into annualized[3] and "per-product" outputs.[4,5] Staff presents both these metrics to convey a holistic perspective of the impact of this rule.

At 100 percent effectiveness, the total estimated societal cost of deaths mitigated by the rule would be $5.23 billion in 2021 dollars over the study period (2024-2053), discounted at 3 percent. However, the rule is expected to eliminate only up to 92 percent of deaths associated

[3] An annualized output converts the aggregate benefits over 30 years into a consistent annual amount while considering the time value of money. This metric is helpful when comparing the benefits among different rules or policy alternatives that may have different timelines, or those that have similar timelines, but benefits for one are front-loaded, while the other's benefits have a latent effect.

[4] A per-product metric expresses the benefits from the rule in one unit of product. This metric is helpful when assessing the impact in marginal terms, for example, comparing benefits to an increase in retail price or marginal increase in cost of production per-unit.

[5] The timing of benefits along the period of study affects the present value of benefits when considering the time value of money. Benefits realized several years into the future are discounted more heavily than benefits realized in the short term.

with entrapment and strangulation (baseline efficacy rate). Additionally, the effectiveness of the rule depends, to some extent, on consumers installing the product correctly; meaning, there may still be some deaths resulting from improper installation or installation on mattresses of inappropriate thickness for use with the product. Staff stress-tested benefits under the scenarios of 75 percent, 50 percent, and 25 percent efficacy. The results are presented below in Table C.1.

Table C.1: Total Benefits, Total, Annualized, and per APBR

Benefits Discounted at 3%	Effective Rates		
	75%	50%	25%
Total Benefits (2024-2053 in $B)	$3.92	$2.62	$1.31
Annualized Benefits (in $M)	$200.24	$133.49	$66.75
Per-Unit Benefits (in $)	$331.78	$221.19	$110.59

Refer to Section VI. A. 1 of the Preamble to the NPR for a more detailed discussion of the rule's benefits.

4. Final Regulatory Analysis: Cost Analysis

This section discusses the costs the rule would impose on industry and the market. There are three cost components discussed under this cost section: the cost of implementing an APBR rule that addresses the entrapment and strangulation hazards; the costs associated with government oversight and compliance monitoring (considered negligible); and the deadweight losses or market impacts derived from the implementation of an APBR rule.

Like the benefits estimate, the time span of the cost analysis covers a 30-year period that starts in 2024, which is the expected first full year of implementation of the rule. This cost analysis presents all cost estimates in 2021 dollars. This cost analysis also discounts costs in the future and uses a 3 percent discount rate to estimate their present value.[6]

In this regulatory assessment, staff considers one solution to address known APBR hazards. This solution requires manufacturers to fully redesign their APBR models to comply with ASTM F3186 – 17, with the modifications included in the final rule. Staff assumed that 100 percent of manufacturers will adopt this solution and estimated the full cost of the rule based on that assumption. Table C.2 summarizes the rule's aggregate total costs, by cost component, over the 30-year study period.

[6] Discounting future estimates to the present allows staff not only to consider the time value of money, but also the opportunity cost of the investment, which is, the value of the best alternative use of funds.

Table C.2: Costs of the Final Rule over 30 Years

Costs of Final Rule	Undiscounted ($M)	Present Value at 3% ($M)
Cost of Redesigning Existing Models	$2.75	$2.59
Cost of Production of Redesigned APBRs	$60.43	$35.65
Deadweight Loss	$2.07	$1.23
Total Costs	**$65.24**	**$39.46**

Please refer to Section VI. A. 2. of the Preamble to the NPR for a more detailed discussion of the estimation methods used to generate the costs of redesigning and manufacturing compliant APBRs (including forecasting the number of models to be redesigned and the number of APBRs to be manufactured), the use of cost improvement curves, the estimation of deadweight loss, and the total cost of the rule (annualized and per APBR, undiscounted and discounted at 3 percent).

5. Benefits and Cost Analysis

Table C.3 below displays metrics for the benefits and costs of the draft final rule. The table displays net benefits (difference between benefits and costs) and the benefit-cost ratio (benefits divided by costs) to assess the cost-benefit relationship. The table displays these metrics using annualized benefits for the three scenarios: 75 percent, 50 percent, and 25 percent efficacy rates. These metrics show the draft final rule's benefits well exceed costs in each scenario.

Table C.3: Annualized Net Benefits of Final Rule

Annualized Net Benefits ($M, Discounted at 3%)	Portion of Benefits Achieved over the Baseline Efficacy Rate of Redesigned APBRs		
	75%	50%	25%
Benefits	$200.24	$133.49	$66.75
Costs	$2.01	$2.01	$2.01
Net Benefits (Benefits-Costs)	$198.23	$131.48	$64.73
B/C Ratio	99.45	66.30	33.15

Table C.4 compares the benefits and costs on a per-unit basis, to add a marginal value perspective.[7] These metrics show the draft proposed rule's benefits well exceed costs at each scenario.

[7] Average undiscounted benefits are calculated by summing the benefits from the draft proposed rule over the 2024–2053 study period and dividing by the number of APBRs produced during the same period. Average undiscounted costs are similarly calculated. Present Values are calculated by determining the benefits and costs of the final rule in the year in which they were

Table C.4: Per-APBR Net Benefits of Final Rule

Per Unit Net Benefits ($, Discounted at 3%)	Portion of Benefits Achieved over the Baseline Efficacy Rate of Redesigned APBRs		
	75%	50%	25%
Benefits	$331.78	$221.19	$110.59
Costs	$3.34	$3.34	$3.34
Net Benefits (Benefits-Costs)	$328.45	$217.85	$107.26
B/C Ratio	99.45	66.30	33.15

Section VI. A. 3 of the preamble of the NPR provides additional discussion of the benefit and cost analysis assessing the relation between the benefits and costs of the rule, including annualized net benefits and benefits per APBR (discounted at 3 percent), and a sensitivity analysis which considers the potential benefits associated with preventing non-fatal APBR-related injuries.

6. Staff Evaluation of the Voluntary Standard

Based on CPSC testing and interviews with suppliers, CPSC staff assessed there is not substantial industry compliance with the voluntary standard at this time. Furthermore, staff assesses substantial future industry compliance is unlikely without the rule because firms have had years to comply with the voluntary standard, but have yet to do so, despite repeated outreach and testing by CPSC staff. Staff has not found any APBR that fully complies with the voluntary standard. Staff also assesses that modifications to the voluntary standard are needed to adequately address the hazard; these modifications are explained in further detail in the "Modifications to ASTM F3186 – 17 As Proposed in § 1270.2 of the NPR" of this briefing package.

Section VI. B. of the preamble of the NPR, provides additional discussion of staff's evaluation of industry compliance with the voluntary standard.

7. Alternatives to the Final Rule

Staff considered six alternatives to the final rule: (1) Take no regulatory action; (2) Continue to conduct recalls of APBRs instead of promulgating a final rule; (3) Conduct an educational campaign; (4) Ban APBRs from the market entirely; (5) Require enhanced safety warnings without other requirements; and (6) Implement the rule with a later effective date. Staff does not recommend any of these alternatives as discussed below.

incurred and discounting those values by 3 percent for each future year. The present values are summed over the 30-year study period and divided by the number of APBRs produced during this same period. Net benefits and benefit-cost ratios are calculated as previously stated.

7.1. No Regulatory Action

If the Commission opted to take no regulatory action, the industry foreseeably would continue in its current state, and consumers would remain at risk of entrapment and strangulation. Rates of injuries and deaths would likely increase with the use of APBRs over time, and the estimated $298.11 million average annualized societal costs would continue to be incurred by consumers in the form of deaths and injuries. For this reason, staff does not recommend this alternative.[8]

7.2. Conduct Recalls Instead of Promulgating a Final Rule

The Commission could seek voluntary or mandatory recalls of APBRs that present a substantial product hazard. With this alternative, manufacturers could continue producing noncompliant products without incurring any additional costs to modify or test APBRs for compliance with the draft final rule. Furthermore, recalls only apply to an individual manufacturer and product, but do not extend to similar hazardous products. Recalls also occur only after consumers have purchased and used such products with possible resulting deaths or injuries due to exposure to the hazard. Additionally, recalls can only address products that are already on the market but do not directly prevent unsafe products from entering the market. As described in TAB A of this Briefing Package, recalls have removed several APBR models from the U.S market since 2021. However, despite these efforts, APBR sales volume remains at, or near, the 2020 pre-recall level and non-compliant APBRs remain available for purchase, which is to be expected given the APBR market's low barriers to entry. Therefore, a significant portion of the estimated $298.11 million average annualized societal costs would likely continue to be incurred by consumers in the form of deaths and injuries. Further, even if recalls had reduced the size of the APBR market or the share of the market comprised of non-compliant APBRs, staff assesses the rule's benefits still would exceed the rule's costs. As shown in Table C.4, the draft final rule provides significant benefits that far exceed costs even if the draft final rule is only 75%, 50% or 25% effective. For these reasons, staff does not recommend this alternative.

7.3. Conduct Education Campaign on the Potential Risks Associated with APBR Use Instead of Promulgating the Final Rule

The Commission could issue press releases or use marketing techniques to warn consumers about the entrapment and strangulation hazards associated with APBRs, instead of issuing a mandatory rule. Information and marketing campaigns may reduce the number of injuries and societal costs associated with APBR entrapment and strangulation hazards. However, marketing campaigns have historically been less effective than designing the hazard out of the product or guarding the consumer from the hazard in the first instance. Therefore, information and marketing campaigns warning customers of APBR entrapment and strangulation hazards

[8] Societal costs from nonfatal injuries associated with APBR use are excluded due to ambiguity in the NEISS case descriptions that prevented definitive in-scope/out-of-scope determinations in almost all cases. Inclusion of nonfatal injury costs increases societal costs to $806.921 million.

are not likely to be as effective in reducing the risk of injury as the proposed draft final rule. Therefore, staff does not recommend this alternative.

7.4. Ban APBRs from the Market

The Commission could issue a total ban of APBRs. Staff weighed both quantifiable factors and unquantifiable factors of APBR use to the individual in making a recommendation regarding this alternative. Use of APBRs provides many unquantifiable benefits to users, including mobility, ease of access to beds, protection against falls, and the potential for at-home care. If the Commission promulgated a rule banning APBRs, the benefits from reduced deaths and injuries would be significant. However, the value of individual users' lost utility could outweigh the benefits. Considering both the quantifiable and unquantifiable costs and benefits, staff assessed that the net benefits of this alternative are likely less than those of the final rule. Therefore, staff does not recommend a ban.

7.5. Require Enhanced Safety Warnings on APBRs Without Promulgating the Other Requirements in the Final Rule

The Commission could require enhanced safety warnings on APBRs. In making its recommendation regarding this alternative, staff considered the effectiveness of this type of policy historically. Warning labels on APBRs currently have not produced the desired results of reducing entrapment and strangulation injuries and deaths. Per CPSC's Human Factors staff's previous analyses, safety warnings that rely on consumers to alter their behavior to avoid the hazard are less effective than designing the hazard out of the product or guarding the consumer from the hazard in the first instance. Consequently, communicating about hazards through labeling, warnings, and instructions should be viewed as a "last resort" measure that supplements, rather than replace, APBR redesign or guarding the consumer from the product, unless these higher-level, hazard-control efforts are not feasible. Due to the likely continued use of APBRs at similar rates and patterns of use, much of the estimated $298.11 million average annualized societal costs would continue to be incurred by consumers in the form of deaths and injuries. Accordingly, staff does not recommend this alternative.

7.6. Propose Later Effective Dates for the New Rule

The Commission could issue the rule with an effective date longer than 30 days allowing APBR firms additional time to meet the requirements of the draft final rule. Staff recognizes that changes in the draft final rule may take some time for firms to address and to certify based on a reasonable testing program. However, the APBR industry would likely be able to comply quickly with the rule because the modifications needed do not require extensive product redesign, and because manufacturers have long had notice of the requirements of ASTM F3186 – 17 and are; therefore, likely familiar with the rule's core requirements, including the testing requirements. Furthermore, delaying implementation of the rule would also allow the sale of non-compliant products for a longer period of time which would likely result in higher social costs, in the form of

fatal and non-fatal APBR entrapment injuries, in exchange for a limited reduction in the cost of compliance to suppliers. For this reason, staff does not recommend this alternative.

8. Summary of Significant Issues Raised in Comments

The CPSC received seven comments regarding the NPR. Some of these comments described the possible economic impacts of the rule, including economic impacts on firms, the utility of the product for consumers, hazard costs associated with the product, and alternative actions that the Commission could take. None of these comments, however, resulted in changes to the regulatory analysis. A summary of the significant issues raised by the comments submitted in response to the preliminary regulatory analysis, and a summary of staff's assessment of such issues appear in the Staff Briefing Memorandum. Comments regarding possible economic impact are also discussed in the Appendix to this Tab.

9. References

Refer to the draft NPR Briefing Package, Tab G, Section 8 which may be found at: https://www.cpsc.gov/s3fs-public/ProposedRuleSafetyStandardforAdultPortableBedRails.pdf?VersionId=Ypa89Iczh13C40Tq7EJRSMDZoatChf1.

Appendix to Tab C: Summary of Significant Issues Raised in Public Comments

The CPSC received seven comments submitted in response to the NPR. Some of these comments described possible economic impacts of the rule, including economic impacts on firms, the utility of the product for consumers, costs associated with the product hazard, and alternative actions that the Commission could take. None of the comments, however, resulted in changes to the regulatory analysis or the regulatory flexibility analysis. In this appendix, CPSC staff provide a summary of the significant issues with possible economic impacts and staff's response to those issues.

Effect on Long-term Care Facilities

Comment: Sarina Marlin's comment expresses concern for the effect of the rule on long-term care facilities. Ms. Marlin asserts that "the fatalities associated with bed rails in the home is nearly three times higher than fatalities associated with bed rails in nursing homes, four times higher than in assisted living facilities, and ten times higher than bed rails in residential facilities …" Ms. Marlin suggests consideration of whether the modifications required by the final rule will create a significant reduction in fatalities in professional settings such as long-term care facilities. Ms. Marlin also suggests that noting any change in cost to these facilities in providing bed rails, and asks, "Would this modification cause bed rails to be even less available at these Long Term Care Facilities, and would such an unavailability instead increase the risk of falls for individuals at these facilities?"

Staff response: The comparative fatality estimates between care settings quoted by Ms. Marlin are drawn from information in preamble of the NPR, in which staff identified 158, 50, 40, and 14 fatalities associated with APBR entrapment in homes, nursing homes, assisted care facilities, and residential institutions, respectively. However, a higher number of fatalities in one type of setting may only reflect a higher number of APBR users; one cannot infer from these data points that the fatality rate is lower in professional settings than in the home, or that APBRs in professional settings pose significantly lower risks to the public, without knowing the number of APBRs in use in each setting. CPSC staff did not, and still after the public comment period does not, possess this information. Nor does CPSC staff have data from which estimates of the number of APBRs in use in each setting may be drawn. These data were also not provided in the public comments to the rule.

The type of setting where a fatality occurs was not individually considered when staff assessed the benefits for the NPR or final rule. Instead, staff estimated benefits for all settings combined. Each prevented fatality produces societal benefits at the rate of the Value per Statistical Life (VSL). Benefits outweigh the costs of the rule by a ratio of approximately 99:1 at a 75 percent effective rate and by approximately 33:1 at a 25 percent effective rate. If injury costs associated APBRs are considered, these ratios are approximately 347:1 and 116:1 at 75 percent and 25 percent effective rates, respectively. Staff assesses these benefit-cost ratios would likely still be significantly greater than 1:1 if the analysis was focused exclusively on long-term care facilities.

Staff also notes the minimal cost of compliance per ABPR and assesses that APBRs will continue to be widely available. These factors, combined with projected reduction in deaths of ABPR users, strongly support a finding that the draft final rule will not cause APBRs to be less available at long-term care facilities, and instead will save the lives of residents of these facilities.

Staff did not specifically include costs associated with possible fall-related deaths and injuries resulting from a price-induced decline in APBR availability. This externality is addressed indirectly by the range of effective rates considered in the benefits assessment.

Stockpiling Provision

Comment: Consumer Voice and CANHR submitted comments in favor of the proposed prohibition on stockpiling.

No comments objecting to the proposed prohibition on stockpiling were submitted.

Effective Date

In the NPR, CPSC staff solicited comments regarding the proposed effective date of 30 days from the final rule's publication date in the *Federal Register*. Consumer Voice and CANHR submitted comments in support of the proposed 30-day effective date.

Comments: Consumer Voice found the 30-day effective date to be appropriate and fair, and stated "… manufacturers should not need more than 30 days". They also commented that the ASTM standards went into effect in 2017 and that "Five years is more than enough time to understand the standards and take the steps necessary to comply." CANHR stated "For the reasons the Commission cites, we support the staff's recommendation not to issue the new rule with an introduction time more than 30 days" while also noting that the ASTM voluntary standard has been available since 2017.

Louis A. Ferreira, of Stoel Rives, LLP and representing Stander Corporation, a seller of APBRs, states that "Stander has made a significant investment to produce products consistent with the existing ASTM Standard," and that "it would require a least a year to sell its existing stock that is compliant with the existing ASTM Standard but not the modified ASTM Standard …" Mr. Ferreira further states that, "As the CPSC has found the compliance with the existing ASTM Standard is sufficient to eliminate the "unreasonable" risks posed by APBRs, CPSC should expressly allow manufacturers a reasonable period of time to sell existing stock that complies with the current ASTM Standard" and that "… Stander believes that a reasonable period to sell its ASTM Standard compliant stock would be one year."

Staff response: Staff agrees with Consumer Voice and CANHR that the 30-day effective date is appropriate. While recognizing that changes in the draft final rule may take some time for firms to address and to certify based on a reasonable testing program, staff also notes that delaying implementation of the rule would result in significant societal costs in the form of fatal and non-

fatal APBR entrapment injuries. And, as Consumer Voice and CANHR note, the APBR industry has had more than five years to prepare to meet the requirements of the draft final rule. With respect to Stander, Mr. Ferreira stated it would require at least a year to sell existing stock, which, staff notes, would provide more than sufficient time to modify new production.

Mr. Ferreira's concerns about additional time needed to sell existing stock are unfounded. As stated in §1270.1 Scope, application, and effective date, of the draft final rule (unchanged from the proposed rule) states, "This part 1270 establishes a consumer product safety standard for adult portable bed rails manufactured after [DATE 30 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER]." Therefore, APBRs manufactured prior to the regulation's effective date may be sold even if they do not comply with the standards set forth in the final rule. However, Stander and other manufacturers will be subject to the proposed prohibition on stockpiling which limits the number the APBRs that can be manufactured during the period between the final rule's publication and effective date.

CPSC staff also disagrees with Mr. Ferreira's claim that "the CPSC has found the compliance with the existing ASTM Standard is sufficient to eliminate the "unreasonable" risks posed by APBRs …" As stated in the SUPPLEMENTARY INFORMATION: Part I. Background and Statutory Authority, and elsewhere in the NPR, "… the Commission preliminarily determines that the voluntary standard is not likely to eliminate or adequately reduce the unreasonable risk of injury associated with entrapments on APBRs." It is only with the NPR's proposed modifications that the Commission preliminarily determined the ASTM to adequately reduce unreasonable risk and injury associated with APBR entrapment.

Potential Ban and Product Utility

In the NPR, the CPSC requested public comments regarding a potential ban of APBRs as an alternative to the rule, alternatives to using APBRs, and qualitative or quantitative evidence of the value of APBRs. Public comments are organized by general subject matter in subsections A. through C. Staff responses are presented in subsection D.

A. Comments: Support for Banning APBRs

Comment: Public Citizen strongly urged the CPSC to withdraw its rule and "to instead promulgate a rule under section 8 of the Consumer Product Safety Act (CPSA) declaring all currently marketed adult bed rails to be banned hazardous products." NCHR, Consumer Voice, and CANHR do not currently support a ban. However, they do support a ban on APBRs if the final rule proves to be ineffective in preventing deaths and injuries resulting from APBR entrapment. NCHR "… enthusiastically supports CPSC's plan …" to "consider banning the products if the new standards do not substantially improve their safety." Consumer Voice opposes a ban at this time, but suggests, "Data should be evaluated in five years to determine the need for a ban." Similarly, "CANHR recommends that within no more than five years, after careful monitoring and evaluation of compliance with the regulations and their effect on bed rail

injuries and deaths, the Commission reconsider imposing a ban on products that pose an unacceptable risk."

B. Comments: Alternatives to Using APBRs

NCHR, Consumer Voice, and CANHR, individually or collectively suggested, as alternatives to ABPRs, the following:

- a secured vertical pole to assist patients in getting in and out of bed,
- bed trapezes and adjustable beds as alternatives to helping patients adjust themselves in bed,
- non-slip mattresses and barriers on the edge of the bed with cushioned material to prevent patients from falling out of the bed due to tossing and turning, and
- lowering the bed or placing cushioned floor mats or other similar products on the ground next to the bed to reduce the chances of injury from a fall.

Consumer voice suggested frequent monitoring and specialized care to prevent a person with cognitive impairment from getting out of bed and moving about unsupervised and unassisted. NCHR suggested installing Bed Exit Alarms (BEA) that alert caregivers when patients try to leave their bed. Gloria Black also suggested the "no cost options" of lowering the bed or placing the mattress on the floor to prevent falls, placing cushioning on the floor to prevent severe injury, and placing a sturdy nightstand or table next to the bed to assist individuals in getting in and out of bed.

C. Comments: Qualitative or Quantitative Value of APBRs

Sarina Martin expresses concern that a ban on APBRs will increase the risk of falls in long-term care facilities. Consumer Voice notes some consumers have expressed fears that a ban could limit their ability to leave their beds, lead to a decline in mobility and functioning and therefore increase their dependency, and result in decreased quality of life due to greater isolation. However, Consumer Voice states that they are unaware of any qualitative or quantitative evidence concerning the utility that APBRs have for consumers relative to products that might be used as substitutes in the event APBRs are banned.

D. Staff Response

CPSC staff disagrees that a ban under section 8 of the CPSA, rather than a performance standard for ABPRs, is warranted. Under section 8 of the CPSA, 15 U.S.C. § 2057, to issue a ban, the Commission must find:

- a consumer product is being, or will be, distributed in commerce and such consumer product presents an unreasonable risk of injury; and

- no feasible consumer product safety standard under this Act would adequately protect the public from the unreasonable risk of injury associated with such product.

CPSC staff concurs with NCHR, Consumer Voice, and CANHR regarding a ban on APBRs. Staff assesses a final rule that mandates compliance with the current voluntary ASTM standard, with modifications, will adequately address unreasonable risk of fatal and non-fatal injuries related to APBR entrapment. And while there may be no-cost or low-cost alternatives to the APBRs, consumer behavior and their comments are indicative of tangible and/or intangible benefits from APBR use. Therefore, staff recommends promulgating the final rule and, as data becomes available, assessing its effectiveness.

Tab D: Adult Portable Bed Rail Final Regulatory Flexibility Analysis

United States
Consumer Product Safety Commission
cpsc.gov | info@cpsc.gov | 800.638.2772

Memorandum

TO: Vineed K. Dayal, Project Manager,
Division of Mechanical Engineering,
Directorate for Laboratory Sciences

DATE: June 28, 2023

THROUGH: Alex Moscoso, Associate Executive Director,
Directorate for Economic Analysis

FROM: Rodney R. Row, Economist,
Directorate for Economic Analysis

SUBJECT: Adult Portable Bed Rail Final Regulatory Flexibility Analysis

---

Introduction

On November 9, 2022, the Commission published a notice of proposed rulemaking (NPR), proposing to issue a safety standard for adult portable bedrails under the Consumer Product Safety Act and seeking public comments. Before a final rule is issued, Section 604 of the Regulatory Flexibility Act requires the Commission to prepare a Final Regulatory Flexibility Analysis (FRFA), describing the impact of the rule on small entities and identifying efforts by the Commission to reduce those impacts.

- a statement of the need for, and objectives of, the rule;
- a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;
- a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and

- a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

Need for, and Objectives of, the Rule

The intent of the draft final rule is to reduce deaths and injuries resulting from entrapment, falls, and other APBR hazards. CPSC staff identified 310 fatal injuries and 1,946 nonfatal injuries associated with APBR hazards in years 2003 through 2021. Of the fatal injuries, approximately 92 percent were related to APBR entrapment hazards. CPSC staff assesses compliance with the voluntary standard, ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*, with modifications, would substantially reduce fatal and nonfatal injuries associated with APBR hazards. Staff recommends the Commission issue the draft final rule because there is no evidence of substantial industry compliance, with the voluntary standard.[1]

At the time of this memorandum, no other federal rules duplicate, overlap, or conflict with this final rule.

Significant Issues Raised by the Public Comments

The CPSC received a total of seven comments submitted by the public in response to the NPR. Some of these comments described possible economic impacts of the rule, including economic impacts on firms, the utility of the product for consumers, costs associated with the product hazards, and alternative actions that the Commission could take. However, none of the comments specifically addressed, or resulted in changes to, the regulatory flexibility analysis. CPSC staff provides a summary of the significant issues with possible economic impacts and a summary of staff's assessment of such issues in the Appendix to Tab C (Row, 2023).

Comments Filed by the Chief Counsel for Advocacy of the Small Business Administration

Chief Counsel for Advocacy of the Small Business Administration did not file a comment on the NPR.

Small Entities to Which the Rule Will Apply

The draft final rule would apply to all manufacturers and importers of APBRs. Manufacturers and importers of APBRs are considered small entities if they are below the size standards (thresholds) established by the U.S. Small Business Administration (SBA).

[1] In both iterations of compliance testing, CPSC staff found all tested APBRs failed at least one critical ASTM F3186-17 requirement. Three APBR firms are participating in CPSC voluntary recalls and are in the process of redesigning their products to comply with ASTM F3186-17.

- APBR manufacturers are classified in the North American Industrial Classification (NAICS) categories 339112 (Surgical and Medical Instrument Manufacturing), 339113 (Surgical Appliance and Supplies Manufacturing), or possibly 339999 (All Other Miscellaneous Manufacturing). SBA size standards for NAICS classifications 339112, 339113, and 339999 are 1,000, 750, and 500 employees, respectively. Staff identified seven domestic APBR manufacturers that are below these thresholds and can be considered small businesses.
- APBR importers could be wholesale or retail distributors. APBR wholesalers may be classified in NAICS category 423450 (Medical, Dental and Hospital Equipment and Supplies Merchant Wholesalers). APBR retailers may be classified in NAICS category 446199 (All Other Health & Personal Care Stores), or possibly in NAICS category 621610 (Home Health Care Services). The SBA size standards for these NAICS classifications are 200 employees, $8 million, and $16.5 million, respectively. CPSC staff identified one domestic APBR firm in these categories that could be considered a small business.[2]

Projected Reporting, Recordkeeping, and other Compliance Requirements

A. Compliance, Reporting, and Record-Keeping Requirements of the Final Rule

The draft final rule would establish performance requirements and test procedures that suppliers would have to meet to sell APBRs in the United States. These requirements and test procedures are detailed in Howie, 2023 (Tab B). In summary, APBRs sold in the United States must comply with ASTM F3186-17 standard with the modifications included in the final rule and be tested and certified to the mandatory standard.

In 2019 and 2020, CPSC staff tested samples of certain APBR models for compliance with ASTM F3186-17. None of the models met the performance requirements of the voluntary standard. A second round of testing in 2021 yielded the same result. Therefore, CPSC staff expects most APBR manufacturers, including those considered small by SBA standards, would incur costs associated with bringing their APBRs into compliance with the rule, as well as costs related to testing and issuing a General Certificate of Conformity (GCC).

In accordance with Section 14(a)(1) of the CPSA, manufacturers would be required to issue a GCC for each APBR model, certifying that the model complies with the draft final rule. According to Section 14(a)(1) of the CPSA, GCCs must be based on a test of each product, or a reasonable testing program; and GCCs must be provided to all distributors or retailers of the product. The manufacturer would have to comply with 16 CFR part 1110 concerning the content of the GCC, retention of the associated records, and any other applicable requirement.

[2] Staff used business profiles and other information from ReferenceUSAGov and Dun & Bradstreet to identify businesses that meet these criteria.

B. Potential Impact on Small Entities

One purpose of the RFA is to evaluate the impact of a regulatory action on small entities and to determine whether that impact is economically significant. Although the SBA allows considerable flexibility in determining what constitutes an "economically significant" impact, CPSC staff typically uses 1 percent of gross revenue as the threshold for determining "economically significant," and prepares an IRFA if it cannot demonstrate that the impact to any firm is less than economically significant.[3]

1. Impact on Small Manufacturers

The final regulatory analysis (Tab C) discusses costs in more detail. Based on that analysis, to achieve compliance with the final rule's performance requirements, APBR suppliers would incur costs from redesigning, retooling, and testing. Staff estimated this cost to be $42,239 per model in the first year. This figure includes $4,532 in compliance testing costs per model.[4] Staff estimated the additional production cost for labor and material to be $5.40 per unit produced in the first year, of which $4.00 is expected to be passed on to the consumer. The figures above include reporting or recordkeeping requirements resulting from the final rule.

Staff identified seven APBR manufacturers that meet SBA size standards for small businesses. Staff applied both the per-model and per-unit costs to each manufacturer's number of models and estimated number of units sold in calendar year 2021. Staff found that the cost to comply with the final rule exceeds one percent of reported annual revenue for three of the seven manufacturers identified as small businesses. For these three APBR manufacturers, the economic impact of the rule is expected to be significant.

2. Impact on Small Importers

Staff identified one possible importer of APBRs from foreign suppliers that would be considered small businesses based on SBA size standards. Small importers would be adversely impacted by the final rule if its foreign supplier withdrew from the U.S. market, rather than incur the cost of compliance. Small importers would also be adversely impacted if foreign manufacturers failed to provide a GCC and the importers had to perform their own testing for compliance. If sales of APBRs are a substantial source of the importer's business, and the importer cannot find an alternative supplier of APBRs, the economic impact on these firms may be significant. However, CPSC staff estimates the U.S. APBR market will grow at annual rate of approximately 2.01 percent over the next 20 years and considers it unlikely that foreign manufacturers would exit a growing market. APBR importers also import other medical equipment, devices, and supplies.

---

[3] The 1 percent of gross revenue threshold is cited as example criteria by the SBA and is commonly used by agencies in determining economic significance (see U.S. Small Business Administration, Office of Advocacy. *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act and Implementing the President's Small Business Agenda and Executive Order 13272*. May 2012, pp 18-20. http://www.sba.gov/sites/default/files/rfaguide_0512_0.pdf)

[4] Testing may be performed by the manufacturer or by third-party engineering consulting or testing firms.

For these firms, any decline in APBR sales and revenue may be partially or fully offset by sales and revenues from other products.

Small importers would be responsible for issuing a GCC certifying that their APBRs comply with the rule's requirements. However, importers may issue GCCs based upon certifications provided by or testing performed by their suppliers. The impact on small importers whose suppliers provide GCCs should not be significant. If a small importer's supplier does not provide the GCC or testing reports, then the importer would have to certify each model for conformity based on a reasonable testing program. Importers would likely contract with an engineering consulting or testing firm to conduct the certification tests. As mentioned above, staff estimated certification testing to be $4,532 per model. This amount is unlikely to exceed 1 percent of the total revenue of this small importer, assuming this firm continues to import the same mix of products it imported before the rule.

Other Significant Alternatives to the Rule Considered

Staff considered six alternatives to the final rule: (1) Take no regulatory action; (2) Conduct a recall of APBRs instead of promulgating a final rule; (3) Conduct an educational campaign; (4) Ban APBRs from the market entirely; (5) Require enhanced safety warnings; and (6) Implement the final rule with a later effective date. Each of these alternatives could reduce the burden on small entities. Staff does not recommend these alternatives for the following reasons:

No Regulatory Action

If the Commission opted to take no regulatory action, the industry foreseeably would continue in its current state, and consumers would remain at risk of entrapment and strangulation. Rates of injuries and deaths would likely increase with the use of APBRs over time, and the estimated $298.11 million[5] average annualized societal costs would continue to be incurred by consumers in the form of deaths and injuries. For this reason, staff does not recommend this alternative.

Conduct Recalls Instead of Promulgating a Final Rule

The Commission could continue voluntary or potential mandatory recalls of APBRs that present a substantial product hazard. With this alternative, manufacturers could continue producing noncompliant products without incurring the additional costs to modify, redesign, and test APBRs to comply with the draft final rule. Furthermore, recalls only apply to individual manufacturers and products subject to the recall, but do not extend to similar hazardous products. Recalls also occur only after consumers have purchased and used the products with possible resulting fatal and non-fatal injuries due to exposure to the product hazard. Additionally, recalls can only address products that are already on the market and do not directly prevent unsafe products from entering the market. As described in TAB A of this Briefing Package, recalls have removed several APBR models from the U.S market since 2021.

[5] Societal costs from nonfatal injuries associated with APBR use are excluded due to ambiguity in the NEISS case descriptions that prevented definitive in-scope/out-of-scope determinations in almost all cases. Inclusion of nonfatal injury costs increases societal costs to $806.921 million.

However, despite these efforts, APBRs sale volume remains at, or near, the 2020 pre-recall level. Therefore, much of the estimated $298.11 million average annualized societal costs would continue to be incurred by consumers in the form of deaths and injuries. Further, even if recalls had reduced the size of the APBR market or the share of the market comprised of non-compliant APBRs, staff assesses the rule's benefits would exceed the rule's costs as explained in the Final Regulatory Analysis (TAB C). For these reasons, staff does not recommend this alternative.

Conduct Education Campaign on the Potential Risks Associated with APBR Use Instead of Promulgating the Final Rule

The Commission could issue press releases or use marketing techniques to warn consumers about entrapment and strangulation hazards associated with APBRs, instead of issuing a mandatory rule. Information and marketing campaigns may reduce the number of injuries and societal costs associated with APBR entrapment and strangulation hazards. However, marketing campaigns have historically been less effective than designing the hazard out of the product or guarding the consumer from the hazard in the first instance. Therefore, information and marketing campaigns warning customers of APBR entrapment and strangulation hazards are not likely to be as effective in reducing the risk of injury as the draft final rule. Therefore, staff does not recommend this alternative.

Ban APBRs from the Market

The Commission could issue a total ban of APBRs. Staff weighed both quantifiable factors and unquantifiable factors of APBR use to the individual in making a recommendation regarding this alternative. Use of APBRs provides many unquantifiable benefits to users, including mobility, ease of access to beds, protection against falls, and the potential for at-home care. If the Commission promulgated a rule banning APBRs, the benefits from reduced deaths and injuries would be significant. However, the value of individual users' lost utility could outweigh the benefits. Considering both the quantifiable and unquantifiable costs and benefits, staff assessed that the net benefits of this alternative are likely less than those of the final rule. Therefore, staff does not recommend a ban.

Require Enhanced Safety Warnings on APBRs Without Promulgating the Other Requirements in the Final Rule

The Commission could require enhanced safety warnings on APBRs. In making its recommendation regarding this alternative, staff considered the effectiveness of this type of policy historically. Warning labels on APBRs currently have not produced the desired results of reducing entrapment and strangulation injuries and deaths. Per CPSC's Human Factors staff's previous analyses, safety warnings that rely on consumers to alter their behavior or avoid the hazard are less effective than designing the hazard out of the product or guarding the consumer from the hazard in the first instance. Consequently, communicating about hazards through labeling, warnings, and instructions should be viewed as a "last resort" measure that supplement, rather than replace, APBR redesign or guarding the consumer from the product,

unless these higher-level, hazard-control efforts are not feasible. Due to the likely continued use of APBRs at similar rates and patterns of use under this alternative, much of the estimated $298.11 million average annualized societal costs would continue to be incurred by consumers in the form of deaths and injuries. Accordingly, staff does not recommend this alternative.

Propose Later Effective Dates for the New Rule

The Commission could issue the rule with an effective date longer than 30 days allowing APBR firms additional time to meet the requirements of the draft final rule. Staff recognizes that changes in the draft final rule may take some time for firms to address and to certify based on a reasonable testing program. However, the APBR industry would likely be able to comply quickly with the rule because the modifications needed do not require extensive product redesign, and because manufacturers have long had notice of the requirements of ASTM F3186 – 17 and are; therefore, likely familiar with the rule's core requirements, including the testing requirements. Furthermore, delaying implementation of the rule would also allow the sale of non-compliant products for a longer period of time which would likely result in higher social costs, in the form of fatal and non-fatal APBR entrapment injuries, in exchange for a limited reduction in the cost of compliance to suppliers. For this reason, staff does not recommend this alternative.

Conclusion

Staff identified seven manufacturers that meet the SBA criteria to be categorized as a small entity. For three of these firms, the estimated cost from the draft final rule is expected to exceed 1 per percent of annual revenue, which staff considers as economically significant.

Staff has identified one importer of foreign manufactured APBRs that meets the SBA criteria to be categorized as a small entity. For this small importer, the cost of certification testing is unlikely to exceed 1 percent of annual revenue. Additionally, the foreign manufacturers are likely to provide a GCC certification the small importer can rely on. Furthermore, given the industry is expected to continue to grow, staff does not anticipate foreign manufacturers to exit the industry because of the implementation of the rule. Therefore, staff assesses the rule will not have a significant economic impact on APBR importers.

In summary, the draft final rule is likely to have a significant adverse economic impact on three of the seven identified small APBR manufacturers, but it is unlikely to have a significant direct impact on small APBR importers. Staff considered six alternatives which could reduce the burden on small entities. However, none are consistent with achieving the rule's objective to improve consumer safety.