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approved and signed.

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE
A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON:
OCTOBER 12, 2022

TO: The Commission
 Alberta E. Mills, Secretary

DATE: September 21, 2022

THROUGH: Austin C. Schlick, General Counsel
 J. DeWane Ray, Acting Executive Director

FROM: Daniel R. Vice, Assistant General Counsel,
 Regulatory Affairs
 Hyun S. Kim, Attorney, Regulatory Affairs

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

The Office of the General Counsel (OGC) is forwarding to the Commission a briefing package recommending that the Commission issue a notice of proposed rulemaking pursuant to sections 7 and 9 of the Consumer Product Safety Act, to address the risk of injury associated with adult portable bed rails (APBRs). OGC also is providing for the Commission's consideration a draft proposed rule that establishes requirements for APBRs with a proposed 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 attached document in the *Federal Register*, as drafted.

(Signature)

(Date)



United States
Consumer Product Safety Commission

II. Approve publication of the attached document in the *Federal Register*, with the specified changes.

(Signature)

(Date)

III. Do not approve publication of the attached document in the *Federal Register*.

(Signature)

(Date)

IV. Take other action specified below.

(Signature)

(Date)

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

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

cpsc.gov

THIS DOCUMENT HAS NOT BEEN REVIEWED
OR ACCEPTED BY THE COMMISSION

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

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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: Notice of proposed rulemaking; notice of opportunity for oral presentation of comments.

SUMMARY: The U.S. Consumer Product Safety Commission (Commission or CPSC) has determined preliminarily that there is an unreasonable risk of injury and death associated with entrapment hazards from adult portable bed rails (APBRs). To address these risks, the Commission proposes a rule under the Consumer Product Safety Act (CPSA) to require that APBRs meet the requirements of the applicable voluntary standard on APBRs, with modifications. The Commission is providing an opportunity for interested parties to present written and oral comments on this notice of proposed rulemaking (NPR). Like written comments, any oral comments will be part of the rulemaking record.

DATES: *Deadline for Written Comments:* Written comments must be received by [INSERT DATE THAT IS 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

Deadline for Request to Present Oral Comments: Any person interested in making an oral presentation must send an electronic mail (e-mail) indicating this intent to the Office of the Secretary at cpsc-os@cpsc.gov by [INSERT DATE THAT IS 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: *Written Comments:* Comments related to the Paperwork Reduction Act aspects of the instructional literature and marking requirements of the proposed rule should be directed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to oira_submission@omb.eop.gov. In addition, written comments that are sent to OMB also should be submitted electronically at: www.regulations.gov, under Docket No. CPSC-2013-0022.

Other comments, identified by Docket No. CPSC-2013-0022, may be submitted by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: www.regulations.gov. Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by e-mail, except as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Mail/hand delivery/courier Written Submissions: Submit comments by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may e-mail them to: cpsc-os@cpsc.gov.

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: www.regulations.gov. Do not submit through this website: confidential business information, trade secret information, or other sensitive or

protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier written submissions.

Docket for NPR: For access to the docket to read background documents or comments received, go to: www.regulations.gov, insert the docket number CPSC-2013-0022 into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Vineed Dayal, Directorate for Engineering Sciences, Office of Hazard Identification and Reduction, Consumer Product Safety Commission, National Product Testing and Evaluation Center, 5 Research Place, Rockville, MD 20850; telephone: 301-987-2292; vdayal@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

In 2013, the CPSC received two requests to initiate proceedings under the Consumer Product Safety Act (CPSA) to address an unreasonable risk of injury associated with adult portable bed rails (APBRs). Gloria Black, the National Consumer Voice for Quality Long-Term Care, Consumer Federation of America, and 60 other organizations made one request; Public Citizen Health Research Group made 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 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 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 concerning 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 delivered a briefing package to the Commission (Staff's 2014 briefing package).¹ In that briefing package, staff responded to the comments received on the petition and recommended that the Commission defer a decision on the petition to allow the voluntary standards process to continue until the APBR standard had been developed and evaluated by staff. On April 29, 2014, the Commission voted to defer the petition to allow progress to continue on the 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 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 a briefing package on its review of ASTM F3186–17 (Staff's 2020 briefing package).² Staff's review indicated that ASTM F3186–17, with certain modifications to the labeling, warning statements, and instructional literature,

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

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

would adequately address the hazards identified in the known incident reports. However, when staff assessed compliance to the voluntary standard, as discussed in section IV.B. of this preamble, staff found no market compliance with the voluntary standard. To increase market awareness of and 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 with 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 for all its members to review and disseminate, supplied updated incident data for the subcommittee's review, and participated as technical experts at all subcommittee task groups.

On September 14, 2022, staff provided to the Commission another briefing package on ASTM F3186–17 (Staff's 2022 briefing package).³ Staff's 2022 briefing package updated the Staff's 2020 briefing package with incident data that included all known APBR incidents from January 2003 through September 2021. In addition, staff discussed the results of the two rounds of testing it had conducted on APBRs, and whether there was any change in the levels of compliance in the APBR market. Staff recommended that the Commission grant the petition and direct staff to prepare a briefing package and initiate rulemaking through 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 this NPR. In this proposed rule, the Commission preliminarily determines that

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>

APBRs pose an unreasonable risk of injuries and deaths associated with entrapment hazards.⁴ To address these risks, the Commission proposes to adopt ASTM F3186–17, with modifications, to improve safety. The information discussed in this preamble is derived primarily from CPSC staff's briefing package for the NPR (Staff's NPR briefing package).⁵

This proposed rulemaking 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 commencing this rulemaking by issuing an NPR.

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
- The means to achieve the objective of the rule while minimizing adverse effects on competition, manufacturing, and commercial practices.

Id. 2058(f)(1).

⁴ The Commission voted X-X to approve this notice.

⁵ Available at: _____

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)&(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)&(F).

II. Product Description

There are several types of bed rails available to consumers under CPSC jurisdiction.⁶ 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 of a bed by consumers and are intended to reduce the risk of falling from the bed, assist the consumer in

⁶ Information on adult bed rails regulated by the U.S. Food and Drug Administration (FDA) jurisdiction 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, FDA regulations refer to “movable and latchable side rails.” See 21 CFR.880.5100, 880.5110, 880.5120. The FDA regulates adjustable hospital beds used for medical purposes. 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. APBR intended for use with a non-FDA regulated bed and that are not considered by the FDA to have a medical purpose fall under the CPSC’s jurisdiction. These types of bed rails are within the CPSC’s jurisdiction regardless of the bed’s location (*i.e.*, long-term care facility, hospice, or residence). ASTM F3186-17 (Section 1.3) covers both APBRs that meet the definition of a medical device under FDA’s jurisdiction, and APBRs that are not medical devices, and fall under CPSC’s jurisdiction pursuant to the CPSA.

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



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

Although similar in design, these products may have different functions. Some are meant to keep the occupant from rolling out of bed, and others are intended to assist an occupant in getting in and out of bed or repositioning on the bed surface. Some of these products can serve both functions. Because of the similarity in design and means of attachment to the side of the bed, products intended for both types of uses can have 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, staff estimates that in 2021, the mean retail price is \$50 per APBR; total market revenues are approximately \$9 million; and the number of APBRs sold that year was approximately 180,000 units.

III. Risk of Injury

CPSC staff summarized the data on deaths and injuries involving APBRs (Tab A: Division of Hazard Analysis: Directorate for Epidemiology (EPHA)). 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.

A. CPSRMS

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 around two to three years from date of reporting. As the APBR data in CPSRMS are heavily reliant on death certificates, data collection is ongoing and incident data for 2020, 2021, and 2022 should all 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 ages 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, for example.⁷ 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.

⁷ All of these reported incidents occurred with APBRs that fall under 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	10	0	10
Cancer	7	0	7
Cerebral palsy	6	0	6
Multiple sclerosis	5	0	5
<i>Other*</i>	20	0	20
Unknown/Not Reported	123	21	144

Source: CPSRMS (2003-2021).

*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.

+Table 4 sums to more than 332 due to multiple conditions reported.

B. NEISS

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 appeared to be a statistically significant increasing trend in injuries during this period. Staff's review showed 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 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 ⁸	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: NEISS (2003-2021). Estimates rounded to nearest 100; rows may not add to total due to rounding

The vast majority (88 percent) of 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. This 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

Staff from CPSC's Directorate for Health Sciences (HS) and from the Human Factors Division of the Directorate for Engineering Sciences (ESHF) (Tabs B and C of Staff's NPR

⁸ 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.

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 here: [National Population by Characteristics: 2020-2021 \(census.gov\)](https://www.census.gov/data/tables/time-series/demo/popest/2020s-national-detail.html), <https://www.census.gov/data/tables/time-series/demo/popest/2020s-national-detail.html>.

briefing package) reviewed the incident data to assess the affected population and the hazard modes associated with incidents involving APBRs. Staff found that 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.
- 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 286 incidents 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. This category includes 284 fatalities and two nonfatal injuries from entrapment or wedging between the bed rail and mattress.
- Falls: There were 25 incidents 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. This category includes 23 deaths, one nonfatal knee fracture and one non-injury incident.
- 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 confirmed that APBRs product types, like those shown in Figure 1, were involved in these entrapment incidents. The victim was 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) patient 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 causes 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. Sustained external pressure on the neck can lead to “asphyxia,” defined in medical literature as the failure of cells to thrive in the absence of oxygen. 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.

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

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. The vast majority of nonfatal incident reports (all reports except one) did not list any 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 syndrome¹¹; amyotrophic lateral sclerosis; cancer; cardiovascular disease; and pulmonary disease. Other conditions included victims with stroke, 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 represent the victims in most APBR-related fatalities, are especially vulnerable to such declines. Also, consumers commonly purchase and use APBRs because they require help when getting in or out of bed. Therefore, many APBR users would likely be less capable of escaping an entrapment scenario than the general population.

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 fatality. Staff found that most falls associated with APBRs involve the victim falling against or striking the APBR, but these incident reports usually have limited details. Therefore, the APBRs might have played an

¹¹ A rare genetic disease characterized by neurological and behavioral abnormalities and occurs almost exclusively in males.

incidental role in some of these cases. 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 APBRs. The Commission has preliminarily determined, however, that substantial compliance with the voluntary standard is not likely to eliminate or adequately reduce the risk of entrapments on APBRs without modifications. In addition, based on several rounds of testing of APBRs, conducted by staff as discussed below, the Commission has preliminarily determined that substantial compliance with the voluntary standard is also unlikely. Accordingly, in this rule, the Commission proposes to incorporate by reference ASTM F3186-17, with modifications, to address the entrapment hazards associated with APBRs. CPSC staff's assessment of the provisions of ASTM F3186-17 are summarized below.

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 preliminarily determines that these definitions are appropriate for evaluating 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 a bed that articulates (i.e., is adjustable) must meet the performance requirements when the bed is in the flat and articulated positions.

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 when 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

Staff identified 284 fatal incidents related to rail entrapment. This hazard pattern is the most prevalent among the incidents, accounting for more than 90 percent of all fatal incidents. 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 call for the product to be tested without 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. However, the Commission seeks comment on whether this sufficiently reduces the risk, or if other measures, are needed.

b. 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 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 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. For example, 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. This minimum height requirement for APBRs may address

some fall incidents by limiting the ability of consumers to climb over these products. 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. In accordance with the entrapment test methods specified in Section 8 of the standard, 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.¹² 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. ASTM F3186-17 specifies the FDA probe 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 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 zones require using a force gauge to test the force applied on the test probe (Section 7.3). Table 6 below, describes the

¹² 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.

four entrapment zones, with illustrations from the 2006 FDA guidance document of sample entrapments within each of these zones.

Table 5: ASTM F3186 – 17 Entrapment Zones

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

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.

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 that rail entrapments predominantly occur in Zones 1 through 4 is also 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 proposed modifications, as discussed in section V. of this preamble.

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. The space between the APBR and headboard or footboard is considered Zone 6 under the 2006 FDA guidance document. ASTM F3186–17 requires the consumer to correctly install the APBR 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 this preamble, the Commission preliminarily determines that, without additional modifications, the voluntary standard is insufficient to eliminate or adequately reduce the unreasonable risk of injury of entrapments on 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, 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 APBR Market Compliance Testing

From 2018 through 2019, CPSC’s Directorate for Laboratory Sciences, Division of Mechanical Engineering staff tested 35 randomly selected APBR models for compliance with ASTM F3186–17, which became effective in August 2017. APBRs were purchased in 2018. Staff tested the products to determine if they conformed to the general requirements and the performance requirements of the standard. Staff also tested conformance with the labeling, warning, and instructional literature requirements. Staff found that none of the 35 sampled products conformed to the voluntary standard. Staff assessment showed that market compliance with the standard was low when staff purchased the samples in 2018, after the standard had become effective. However, due to the lack of compliant labeling, staff could not confirm all the manufacture dates for the products to compare them to the standard’s effective date. As shown in Table 8 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 7: ASTM F3186–17, 2018 APBR Market Compliance Testing Result Summary

Section		Title	# of Failed Samples	Failure Rate
			(of 35 Total Samples Tested)	
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.

Staff's testing also revealed high failure rates in several other sections, 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,¹³ 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 APBRs; 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 APBR Market Compliance Testing

In 2021, CPSC 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 was sufficient for manufacturers to increase their overall level of compliance to the standard. A representative 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 remaining models available in the market. The nine randomly selected models were products previously identified as available in the 2018 analysis,

¹³The proposed 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.

and were included to account for any undisclosed changes to the 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 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 testing of a sample was stopped after it failed 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 changes 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

4. Section 15 Compliance Actions 2021 – 2022

CPSC has issued five public notices regarding 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.¹⁴ Bed Handles, Inc., manufactured approximately 193,000 units of the bed rails, and CPSC is aware of four entrapment deaths associated with them.

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);¹⁵
- Compass Health Brands (104,900 units, 3 deaths); and¹⁶
- Essential Medical Supply, Inc. (272,000 units, 1 death).¹⁷

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 model have occurred.¹⁸ Neither firm agreed to conduct a recall. Approximately 285,000 units were manufactured.

¹⁴ 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>.

¹⁵ PR #22-025, <https://www.cpsc.gov/Recalls/2022/Drive-DeVilbiss-Healthcare-Recalls-Adult-Portable-Bed-Rails-After-Two-Deaths-Entrapment-and-Asphyxiation-Hazards>.

¹⁶ 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>.

¹⁷ 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>.

¹⁸ 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>.

5. APBR Market Compliance Testing Summary

As discussed in section V. of this preamble, the Commission preliminarily determines that, without additional modifications, the voluntary standard is insufficient to eliminate or adequately reduce the unreasonable risk of injury of entrapments on APBRs. Moreover, based on staff's test results showing that there is no market compliance with the voluntary standard, the Commission preliminarily determines that substantial compliance to a voluntary adult portable bed rail safety standard is unlikely. Accordingly, the Commission proposes to incorporate by reference, ASTM F3186-17 with modifications, to require APBR manufacturers to comply with the mandatory standard and thereby improve safety.

V. Proposed Requirements

The Commission preliminarily determines that ASTM F3186-17, with modifications to improve safety, would likely address all known product hazard modes associated with APBRs, and particularly entrapment. These modifications are as follows:

- provide additional definitions for product “assembly” and “installation” to ensure their consistent and differentiated use throughout the document;
- include recommendations for manufacturers to take into account the range of mattress thicknesses to ensure safe use of the product by the consumer and provide testers with additional guidance for selecting the mattress thickness during the test setup;
- address inconsistencies with stated dimensions to ensure consistent dimensional tolerances;
- provide additional clarity for Zone 1 and 2 test setup and methods;
- provide additional guidance for identifying potential Zone 2 openings;
- update the requirements for Zone 3 testing for consistency; and

- make grammatical and editorial corrections.¹⁹

A. Description of Proposed Section 1270.1 – Scope, Application, and Effective Date

Proposed section 1270.1 provides that new part 1270 establishes a consumer product safety standard for APBRs manufactured after 30 days after publication of the final rule in the *Federal Register*.

B. Description of Proposed Section 1270.2 – Requirements for Adult Portable Bed Rails

Proposed section 1270.2 sets forth the requirements for APBRs that are required in addition to those required by ASTM F3186-17. Section 1270.2(a) would require each APBR to comply with all applicable provisions of ASTM F3186-17 with the following changes as set forth in section 1270(b):

1. *Propose New Clarifying Definitions on “Assembly”, “Installation” and “Component”* (§§ 3.18, 3.1.9, 3.1.10).

The Commission proposes to add the following new definitions to ASTM F3186-17.

- § 3.1.8: *Initial Assembly*, the first assembly of the product components after purchase, and prior to installing on the bed.
- § 3.1.9: *Initial Installation*, the first installation of the product onto a bed or mattress.
- § 3.1.10: *Installation Component*, component(s) of the bed rail that is/are specifically designed to attach the bed rail to the bed and typically located under the mattress when in the manufacturer’s recommended use position.

These proposed 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, as discussed below. Although “installation component” is used throughout the voluntary standard, it

¹⁹ Tab F of Staff’s NPR briefing package provides a redline version in sequential order as the sections appear in ASTM F3186-17.

was not explained. The new proposed definition helps clarify the location of warnings from section 9.2.7.

2. Propose Clarifications to Sections 6.1.3 and 9.2.7.

The Commission proposes to revise sections 6.1.3 and 9.2.7 with the definitions provided in proposed sections 3.1.8, 3.1.9 and 3.1.10 as follows:

- § 6.1.3: Revise “Permanently attached retention system components shall not be able to be removed without the use of a tool after initial installation” by changing “initial installation” to “initial assembly.”

Staff’s review shows that 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 hazards. The additional definitions make clear that retention system should remain attached to the product and should not be compromised after initial assembly and between uninstallation, and reinstallation of the product.

- § 9.2.7: Revise “At least one conspicuous component of the product must be labeled with the following entrapment warning” by changing “conspicuous component” to “installation component.”

▲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.

•

Staff’s review demonstrates that this warning is intended to draw attention to the installation component and to encourage its use. 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 instead draw attention to the installation component. Furthermore, 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 rather than on a conspicuous component.

3. Propose Clarifications to Sections 6.5.1 and 6.5.2

The Commission proposes to clarify the following sections of ASTM F3186-17:

- § 6.5.1: Revise “Any structural components and retention system components of a product covered by this specification that require consumer assembly shall not be able to be misassembled when evaluated to 6.5.2” to “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.”

This revision clarifies that disassembly with the use of a tool is not considered as “misassembly” under section 6.5.

§ 6.5.2: Revise “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.”

This editorial change corrects the misspelling of “misassembled” to “misassembled.”

4. Propose New Sections to Address Mattress Variability (§ 6.2.1.1, § 7.1.3)

Staff's review shows that mattress thickness is a known variable that may cause some APBR product designs to have hazardous entrapment zones. Accordingly, to improve the safety of APBRs, the ASTM F3186-17 requirements should provide additional guidance on what thickness of mattress to use for testing APBR products. The following proposed new sections address this issue:

- § 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.

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.

- § 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. NOTE *: Proposed Mattress

Type Clarification: 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.

Because mattress types are constantly changing, the proposed language in § 6.2.1.1 and § 7.1.3 informs manufacturers and testers to be aware of the types and variability of mattresses consumers may be using with these products and test accordingly. Consumers cannot be expected to be able to consistently measure mattress thickness, nor to purchase a new mattress for proper compatibility with a bed rail. Additionally, consumers are likely to follow nominal thickness descriptors of their mattresses which may vary from actual specifications. This additional range proposed for testing in new proposed § 7.1.3 may be up to 1.5 in (38 mm) larger or smaller than the range specified by the manufacturer, will increase safety by accounting for foreseeable reasonable differences between nominal and actual mattress thicknesses.

5. Propose Revisions to Entrapment Test Probe (§ 7.2) to Update References

- § 7.2: *Entrapment Test Probe*—This section is revised to update references. Currently, ASTM F3186-17 provides that: 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:<http://www.fda.gov/MedicalDeviceRegulationandGuidance/GuidanceDocuments/ucm072662>. The test probe can be independently manufactured or it can be purchased from NST Sales & Customer Service Office, 5154 Enterprise Blvd., Toledo, Ohio 43612, 800-

678-7072, www.nst-usa.com. video illustrating use of the test probe is available at the NST website (free registration required).

To update outdated references, this section is proposed to be changed to state that the FDA guidance may 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 Development Corporation, 5154 Enterprise Blvd, Toledo, OH 43612, 800-551-7096, <https://bionix.com>. Videos illustrating use of the test probe are available at www.youtube.com/c/BionixLLC/search.”

6. Propose Revisions to Performance Requirements for Zone 3 Entrapment (§§ 6.3.3, 8.4.5.4, and 6.4.1)

The Commission is proposing revisions to test for Zone 3 entrapment hazards

- § 6.3.3: Zone 3—Revise “The highest point on the cylinder of the test probe (see 7.2) shall not pass completely below the horizontal uncompressed plane of the mattress when tested according to 8.4.5.” Add at the end of the sentence “...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 7.2) shall be above the highest point of the uncompressed mattress.”
- § 8.4.5.4: Revise “Turn the cone until the centerline on the face of the 4.7 in (119.38 mm) end is horizontal and let the cone sink into the space by its own weight. (1) If the line on the face of the 4.7 in (120 mm) end of the cone is above the surface of the mattress highest point of the uncompressed mattress, as shown in Figure 4a, the space passes the test. (2) If the line on the face of the 4.7 in (120 mm) end of the cone is at or below the surface of the mattress, the space fails the test.” Instead of the “below the surface of the

mattress" insert "below the highest point of the uncompressed mattress, as shown in Figure 4b."

- § 8.4.5.4. Add the following proposed figures (Figure 4a and Figure 4b) for reference for Zone 3 test:

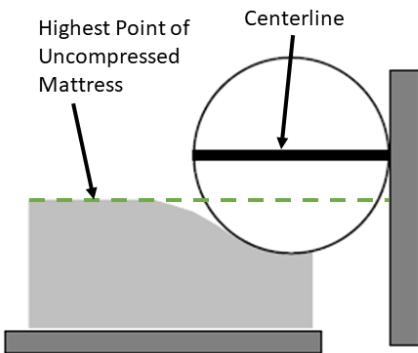


Figure 4a: Zone 3 Pass Criteria
(Centerline above highest point of uncompressed mattress)

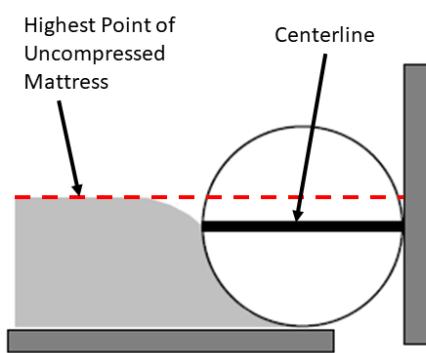


Figure 4b: Zone 3 Fail Criteria
(Centerline below highest point of uncompressed mattress)

CPSC staff's review showed that 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. To ensure consistency, proposed revisions to these sections more accurately describe the test method for the highest level of safety and are also more consistent with the FDA guidance document referenced in the standard. In addition, the Figures 4a and 4b are proposed to assist testers in visualizing the test criteria.

- § 6.4.1 Revise the measurements in "Holes or slots that extend entirely through a wall section of any rigid material less than $\frac{1}{4}$ in (6.35 mm) thick and admit a $\frac{5}{8}$ in (15.9 mm) diameter rod shall also admit a 1 in (25.4 mm) diameter rod. Holes or slots that are between 8 mm and 25 mm and have a wall thickness less than $\frac{1}{4}$ in (6.35 mm) but are limited in depth to $\frac{1}{4}$ in (6.35 mm) maximum by another rigid surface shall be permissible (see Fig. 2)" to the following: "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)."

Staff's review showed that the measurement references in 6.4.1 were not accurate or consistent throughout the section, or the referenced Figure 2. The proposed change to this section fixes those issues and harmonizes the requirements with other established ASTM standards that have similar requirements such as ASTM F2085 (Children's Portable Bed Rails), codified under 16 CFR part 1224.

7. Revise Entrapment Testing Probe Pull Force Application for Entrapment Zones 1 and 2

To make the current language and test method in ASTM F816-17 section 8.4.4 for Zone 2 entrapment testing (*Between the Product Support(s) and the Bed Mattress, When Applicable, Under the Product*) clearer and more repeatable, the proposed rule contains the following changes under section 8.4.4.

- § 8.4.NOTE 1: Revise "The tests described in this section are identical to those described in the referenced FDA Guidance Document and in the NSA video" to "The tests described in this section are similar to those described in the referenced FDA Guidance Document."

Although the FDA guidance document is the source of the entrapment test methodologies, there are several differences in the proposed standard and the FDA guidance document. In addition, the NSA video is not available.

- § 8.4.3.4: Revise “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 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 and pass through any of the openings, this space fails the test” to “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.”

As explained by CPSC staff, 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 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 and 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.

- § 8.4.4.3: Revise “Insert the 2.4 in (60 mm) end of the cone perpendicular to the opening from the longitudinal centerline of the mattress” to “Insert the 2.4 in (60 mm) end of the cone 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.

The intent of this requirement is to address entrapment hazards associated with bed rails and head entrapment in Zone 2 by ensuring that 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 to which the probe is applied.

- § 8.4.4.4: Revise “Using the force gauge, exert a 22.5 lbf (100 N) pulling force to the 2.4 in (60 mm) cylindrical end of cone in both directions perpendicular to the rail” to “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.”

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 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. 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, and also reduces ambiguity.

In addition, to take in account bed rails that have significant overhang, the NPR proposes to add new section 8.4.4.5.

- § 8.4.4.5: If a horizontal section of the rail greater than 4.7 in (120 mm) exists along the bottom of the rail, that section must also meet the Zone 2 requirements.

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 during the

development of the APBR testing procedure, but the overhang could potentially result in a similar entrapment. Thus, the requirements and test methods for these types of openings should be consistent with the Zone 2 requirements as reflected in the proposed language.

8. Propose New Note to Clarify Retention Test

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. Adding this proposed note to explain the location of the “free end” will clarify the test method for testers and make it more repeatable. Accordingly, the Commission proposes to add the following note:

- § 8.6.3 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.

9. Propose Clarifications to Labels and Warning Requirements.

- § 9.1.1.3: Revise “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 either <2.4 in (60 mm) or >12.5 in (318 mm)” to remove “either <2.4 in (60 mm) or” from the last sentence.

This proposed change addresses an inconsistency between section 9.1.1.3, which states that products may be installed <2.4 in or >12.5 in away from head or footboards, and section 9.2.6, which states that products must be installed at least 12.5 in from headboards or footboards.

- § 9.2.5: Revise the warning statement: 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, and 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.

to delete “, and” after “frail”.

This proposed change is a grammatical edit and brings the warning language into alignment with similar language used in section 9.2.6.

- § 11.1.1.3: Revise “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”
to change “is” to “its.”

This proposed change is a grammatical edit.

C. Proposed Findings - § 1270.3

The findings required by section 9 of the CPSA are discussed throughout this preamble and set forth in section 1270.3 of the proposed rule.

VI. Preliminary Regulatory Analysis

Pursuant to section 9(c) of the Consumer Product Safety Act, publication of a proposed rule must include a preliminary regulatory analysis containing:

- A preliminary description of the potential benefits and potential costs of the proposed 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 discussion of why a relevant voluntary safety standard would not eliminate or adequately reduce the risk of injury addressed by the proposed rule.

- A description of any reasonable alternatives to the proposed rule, together with a summary description of their potential costs and benefits and why such alternatives should not be published as a proposed rule.

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

CPSC's preliminary assessment of the potential benefits and costs show that if 92 percent of deaths caused by entrapment are addressed by the proposed rule, the annualized present value of the potential benefits of the proposed rule is \$298.11 million. CPSC also assessed lower efficacy rates of the proposed rule which showed the quantifiable benefits of the proposed rule in the range of \$66.75 million (assuming a 25% efficacy rate) to \$200.24 million per year (assuming a 75% efficacy rate). The costs associated with the proposed 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 proposed rule are estimated between \$110.59 per APBR (25%) and \$331.78 per APBR (75%), and the costs are estimated at \$3.34 per APBR. All these amounts are in 2021 dollars using a discount rate of 3 percent. Staff'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 whether these incidents would be prevented by the proposed rule.

1. Benefits of the Proposed Rule

The potential benefits and costs of the rule are discussed in Tab G of the Staff's NPR briefing package. 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. For the preliminary regulatory analysis, staff chose the period of 2010 through 2019 to base its rates of

fatalities per product because it was the most recent 10-year window where all or nearly all incidents have been reported. Staff 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 proposed rule. To forecast entrapment deaths into the future, staff used death rates per million APBRs in conjunction with its forecast of APBRs in use throughout the study period. Staff assumed deaths would stay the same as the average rates observed between 2010 to 2019: 31.9 deaths per million APBRs. Staff forecasted APBRs in use using the population breakdown by age of APBR users, adjusted for population demographics and the growth of home healthcare spending.

To estimate the societal costs of entrapment deaths, staff applied 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. This is a “willingness to pay” methodology that attempts to measure how much individuals are willing to pay for a small reduction in their own mortality risks, or how much additional compensation they would require to accept slightly higher mortality risks. For this analysis, staff applied estimates 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. Staff multiplied 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 proposed rule.

CPSC staff assumes that the number of firms and APBR 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 year between 2024 and 2053 as a result of an aging U.S. population. Assuming the rates 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 value of a statistical life (VSL) of \$10.5 million (2021 dollars), the annualized present value of the potential benefits of the proposed rule is \$298.11 million.

Staff did not include injuries in its benefit-cost assessment because for many incidents involving injuries, there is not sufficient information to determine whether they would be prevented by the proposed rule. However, staff has quantified and monetized the injuries in a sensitivity analysis as a potential upper limit to assess the benefits of this proposed rule. The requirements of the proposed rule are expected to address 92 percent of deaths caused by entrapment. However, staff also assessed potential benefits under three scenarios derived from this baseline efficacy, estimating benefits at: 75 percent, 50 percent, and 25 percent of their potential value.

At these rates under varying conservative assumptions (*i.e.*, likely to underestimate the benefits of the rule), CPSC staff estimates the annualized benefits of the proposed rule to be \$200.24 million, \$133.49 million, and \$66.75 million, respectively. As discussed below, staff estimates annualized costs associated with the proposed requirements to prevent APBR hazards 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 shows the annualized net benefits under the scenarios.

Table 10: Net Benefits of Proposed 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 11 compares the benefits and costs on a per-unit basis, to add a marginal value perspective.²⁰ These metrics again show the proposed rule’s benefits well exceed costs at each scenario.

Table 11 shows the Per-APBR Net Benefits of the proposed 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

2. Costs of the Proposed Rule

Staff’s regulatory assessment of the costs of the proposed rule assumed that 100 percent of manufacturers will fully redesign their APBR models to comply with ASTM F3186–17, with 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 rule. This cost

²⁰ Average undiscounted benefits are calculated by summing the benefits from the 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 proposed rule in the year in which they were 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.

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.²¹

The cost of implementing an APBR fix to address entrapment hazards includes the costs manufacturers incur to redesign existing models and produce new designs to comply with ASTM F3186–17, as well as any additional cost of producing the APBR that is associated with its redesign. Manufacturers incur design costs that include redesigning existing APBR models, and designing APBR models in the future, to comply with the ASTM F3186 as modified. Manufacturers would likely incur expenditures in design labor, design production, design validation, and compliance testing. 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, staff 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 proposed rule. For this analysis, staff estimated deadweight loss for each year the proposed rule is expected to have an impact on marginal cost and market price.

Table 12 summarizes the cost of the proposed rule:

²¹ 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 12: Total Cost of the Proposed 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
Total Costs	\$65.24	\$39.46

3. Sensitivity Analysis

A major source of uncertainty is the omission of nonfatal entrapment injuries in the benefits assessment. This may result in a significant under-estimation of the benefits of the proposed rule. In its sensitivity analysis, staff included the benefits of averting all nonfatal injuries reported in NEISS, despite the uncertainty of whether these incidents would be in-scope of this proposed rule. These estimates serve as the theoretical upper bound of benefits from the proposed rule.

Staff used NEISS incidents and the Injury Cost Model (ICM) to extrapolate and generate national estimates for injuries from entrapment treated in EDs and other settings. The ICM calculated that there were 125,121 nonfatal injuries from entrapment in the United States from 2010 to 2019. Of this total, 79,563 were treated in an outpatient setting (e.g., doctor's office, or clinic), 39,149 resulted in ED treatment, and 6,409 resulted in hospital admissions. Over 30 years, staff estimates the societal costs from injuries associated with entrapments, annualized and discounted at 3 percent, to be \$195.52 million for doctor's office/clinic, \$179.49 million for ED, and \$289.64 million for hospital admissions.

To forecast injuries from entrapment into the future, staff used injury rates per million APBRs in conjunction its forecast of APBRs in use throughout the study period. Staff assumed injuries would stay the same as the average rates observed between 2010 to 2019: 1,293.6 hospital admissions per million APBRs in use; 7,902.2 ED admissions per million APBRs in

use; and 16,059.7 doctor/clinic visits per million APBRs in use. Staff forecasted APBRs in use based on the population breakdown by age of APBR users, adjusted for population demographics and the growth of home healthcare spending. Staff estimated the societal costs of nonfatal injuries using the ICM. The ICM estimates that the costs (in 2021 dollars) associated with nonfatal entrapment injuries using the quality adjusted life years are: \$15,270 for injuries treated at the doctor's office/clinic; \$28,849 for injuries treated in the ED; and \$280,832 for injuries that result in hospital admission.

Table 13 below displays metrics for the benefits and costs of the proposed 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. These metrics show the proposed rule's benefits well exceed costs in each scenario.

Table 13 displays metrics for benefits, with nonfatal injuries included, and costs of the proposed rule.

Table 13: Net Benefits of Proposed Rule

Portion of Benefits Achieved over the Baseline Efficacy Rate of Redesigned APBRs			
Annualized Net Benefits (\$M, Discounted at 3%)	75%	50%	25%
Benefits	\$698.73	\$465.82	\$232.91
Costs	\$2.01	\$2.01	\$2.01
Net Benefits (Benefits-Costs)	\$696.72	\$463.81	\$230.90
B/C Ratio	347.04	231.36	115.68

Table 14 compares the benefits, with nonfatal injuries included, to costs on a per-unit basis.

Table 14: Per-APBR Net Benefits of Proposed Rule

Per-Unit Net Benefits (\$, Discounted at 3%)	Portion of Benefits Achieved over the Baseline Efficacy Rate of Redesigned APBRs		
	75%	50%	25%
Benefits	\$1,157.74	\$771.83	\$385.91
Costs	\$3.34	\$3.34	\$3.34
Net Benefits (Benefits-Costs)	\$1154.41	\$768.49	\$382.58
B/C Ratio	347.04	231.36	115.68

B. Voluntary Standard

Based on staff's evaluation of ASTM F3186-17, the Commission preliminarily determines that the CPSC could rely on the current voluntary standard, ASTM F3186-17, if it were modified to improve clarity and safety for APBRs. However, as discussed in section II of this preamble, and Tabs C and D of the staff NPR briefing package, 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 thought that their products already conformed; two indicated some modifications were required to bring their products into compliance; and two expressed uncertainty 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 show that there is no substantial industry compliance with the voluntary standard at this time. Furthermore, substantial future industry compliance appears 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 standard.

C. Alternatives to the Proposed Rule

The Commission considered six alternatives to the proposed 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 for APBRs; and (6) a later effective date. The Commission preliminarily 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 to fail to address the entrapment hazards associated with APBRs, and consumers would remain at risk. 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, 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 to recall APBRs in use that present a substantial product hazard. With this alternative, manufacturers would continue to not comply with the voluntary standard and would not incur any costs to modify or test APBRs to comply with the proposed rule. However, recalls only apply to an individual manufacturers and sellers of APBRs, and do

not extend to similar products that fall within the scope of ASTM 3186-17 and present the same hazards. In addition, recalls occur only after consumers have purchased and used such products and may have been killed or injured due to exposure to the hazard. Finally, recalls cannot directly prevent unsafe products from entering the market. 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. For these reasons, 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 news releases or use other information and marketing techniques to warn consumers about entrapment hazards associated with APBRs, instead of issuing a mandatory rule. Information and marketing campaigns, in conjunction with CPSC recall actions, may reduce the number of injuries and societal costs associated with APBR entrapment hazards. However, education campaigns and recalls are not likely to adequately reduce the risk of injury from the entrapment hazard. As noted above, CPSC has issued recall announcements for APBRs in the past, and these have not adequately addressed the entrapment hazard. Furthermore, recalls and associated education campaigns occur only after consumers have been exposed to the hazard and potentially suffered injury or death due as the result. Therefore, the Commission does not find this alternative would adequately address the unreasonable risk of injury associated with APBRs.

4. Total Ban of APBRs from the Market

The Commission could ban APBRs sold as consumer products. However, in considering this alternative, the Commission must weigh both quantifiable and unquantifiable factors of the utility of APBR use to consumers. APBRs provide benefits to users, including mobility, ease of

access to beds, and the potential for at-home care. Considering both the quantifiable and unquantifiable costs and benefits, the net benefit of this alternative is likely less than that of the proposed rule. However, the Commission seeks comments on whether the proposed adoption of the modified ASTM standard sufficiently addresses the hazard and whether a ban is warranted, and if so, what the impact of a ban would be on consumers (e.g., lost consumer utility from not having the product).

5. Enhanced Safety Warnings on APBRs

The Commission could require enhanced safety warnings on APBRs. Warning labels on APBRs have not produced the desired results of reducing entrapment injuries and deaths. 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. Accordingly, the Commission preliminarily finds that warnings alone would not adequately address the unreasonable risk of injury associated with APBRs. Although warnings and instructions have limited effectiveness, the labeling, warning, and instructional literature requirements of ASTM F3186-17 do beneficially address the risk of injuries and deaths associated with APBRs and CPSC proposes that they be adopted with modifications set forth in the proposed rule.

6. Later Effective Date

The Commission could issue the new rule with an introduction time greater than the 30 days recommended in this proposed rule. APBRs that present an unreasonable risk of death or injury from entrapment would continue to enter the marketplace during that time. Delaying the benefits of the rule likely results in higher social costs, in exchange for limited benefits to producers, who would still be required to revise their APBR products. Furthermore, manufacturers of APBRs have long had notice of the requirements of ASTM F3186-17 and, as

staff investigation confirms, are familiar with the core requirements of the proposed rule. For this reason, staff does not recommend this alternative.

VII. Initial Regulatory Flexibility Analysis

Whenever an agency publishes an NPR, Section 603 of the Regulatory Flexibility Act (RFA), 5 USC 601–612, requires agencies to prepare an initial regulatory flexibility analysis (IRFA), unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The IRFA, or a summary of it, must be published in the *Federal Register* with the proposed rule. Under Section 603(b) of the RFA, each IRFA must address:

- (1) a description of why action by the agency is being considered;
- (2) a succinct statement of the objectives of, and legal basis for, the proposed rule;
- (3) a description and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- (4) a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed 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
- (5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule.

The IRFA must also describe any significant alternatives to the proposed rule that would accomplish the stated objectives and that minimize any significant economic impact on small entities. Staff's initial regulatory flexibility analysis is provided in Tab H of Staff's NPR briefing package.

A. Reason for Agency Action

The purpose of the proposed rule is to reduce deaths and injuries resulting from entrapment on APBRs. CPSC staff identified 310 fatal injuries associated with APBR hazards in years 2003 through 2021. Although staff's assessment with ASTM F3186-17 shows that, with modifications, it would adequately reduce the unreasonable risk of injury associated with APBRs, there is no compliance with the voluntary standard. Accordingly, the Commission preliminarily finds that a mandatory rule is reasonably necessary to reduce the unreasonable risk of injury of entrapment hazards from APBRs.

B. Objectives and Legal Basis for the Rule

The Commission proposes this rule to reduce the risk of death and injury associated with APBRs. The rule is promulgated under the authority in sections 7 and 9 of the CPSA.

C. Small Entities to Which the Rule Will Apply

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

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

The proposed rule would establish a performance requirement for APBRs and test procedures that suppliers would have to meet to sell APBRs in the United States. Specifically, the NPR would require APBRs sold in the United States to comply with the ASTM F3186-17 standard, with the proposed 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 proposed rule, as well as costs related to testing and issuing a General Certificate of Conformity (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 proposed rule. According to Section 14 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. Federal Rules that May Duplicate, Overlap, or Conflict with the Proposed Rule

CPSC has not identified any other Federal rules that duplicate, overlap, or conflict with the proposed rule.

F. Potential Impact on Small Entities

Generally, CPSC considers an impact to be potentially significant if it exceeds 1 percent of firm's gross revenue. 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 unit sales in 2021. Staff found that the initial cost to comply with the proposed 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 proposed rule is expected to be significant. As discussed in Tab G of Staff's NPR Briefing Package, to achieve compliance with the proposed rule's performance requirements, APBR suppliers would incur costs from redesigning, retooling, and testing. 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 \$10.01 per unit produced in the first year, of which \$7.74 is expected to be passed on to the consumer.

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 proposed 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, staff estimates the U.S. APBR market will grow at annual rate of approximately 2.01 percent over the next 20 years. It is unlikely that foreign manufacturers would exit a market growing at this rate. APBR importers also import other medical equipment, devices, and supplies. For these firms, any decline in APBR sales and revenue may be partially or fully offset by increasing sales and revenues of these 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. Based on an estimated \$4,532 per model for testing, the impact on small importers whose suppliers provide GCCs is unlikely to be significant.

VIII. Incorporation by Reference

The Commission proposes to incorporate 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, 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 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 proposes to incorporate by reference into 16 CFR part 1270. The standard itself is reasonably available to interested parties. Until the comment period ends, 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.

IX. 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 proposed 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).

X. Preemption

Executive Order (EO) 12988, Civil Justice Reform (Feb. 5, 1996), directs agencies to specify the preemptive effect of a rule in the regulation. 61 FR 4729 (Feb. 7, 1996). The

proposed regulation for APBRs is issued under 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.” *Id.* 2075(a). Thus, the proposed rule for APBRs, if finalized, would preempt non-identical state or local requirements for APBRs 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).

XI. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA). 44 U.S.C. 3501–3520. We describe the provisions in this section of the document with an estimate of the annual reporting burden. Our estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

CPSC particularly invites comments on: (1) whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility; (2) the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; (4) ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and (5) estimated burden hours associated with label modification, including any alternative estimates.

Title: *Safety Standard for Adult Portable Bed Rails*

Description: The proposed rule would require each APBR to comply with ASTM F3186-17, *Standard Specification for Adult Portable Bed Rails and Related Products*, with modifications. Sections 9, 10, and 11 of ASTM F3186-17 contain requirements for labels, warnings and instructional literature.

Description of Respondents: Persons who manufacture or import adult portable bed rails.

Staff estimates the burden of this collection of information as follows in Table 15:

Table 15—Estimated Annual Reporting Burden

Burden Type	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours	Annual Cost
Labeling	12	6	72	8	576	\$20,304
Instructional Literature	12	6	72	24	1,728	\$60,912
Total Burden					2,304	\$81,216

Our estimate is based on the following. There are 12 known entities supplying APBRs to the U.S. market. On average, each entity supplies six APBR models to the market. All 12 entities are assumed to already use labels on both their products and packaging. However, none of the APBR models tested comply with ASTM F3186–17 labeling and informational requirements. CPSC therefore expects all entities will need to make modifications to their existing labels. The estimated time required to make these modifications is about eight hours per model. Each entity supplies an average of six different APBR models. Therefore, the estimated burden associated with labels is 576 hours (12 entities \times 6 models per entity \times 8 hours per model = 576 hours). We estimate the hourly compensation for the time required to create and update labels is \$35.25 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” March 2022, total compensation for all sales and office workers in goods-producing private industries: www.bls.gov/ncs/.) Therefore, the estimated annual cost to industry associated with the labeling requirements is \$20,304 (\$35.25 per hour \times 576 hours). There are no operating, maintenance, or capital costs associated with the collection.

The proposed rule would also require instructions to be supplied with the product. Under the OMB's regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the “normal course of their activities” are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are “usual and customary.” APBRs require installation on an existing bed, which implies instructions for proper use, fit, and position on a bed, as well as cleaning are necessary. While many APBR entities already provide some instructional material, CPSC expects all will need to make some modifications to existing material. The estimated time to modify the instructional material is 24 hours per model. Each

entity supplies an average of six different APBR models. Therefore, the estimated burden associated with instructional literature is 1,728 hours (12 entities \times 6 models per entity \times 24 hours per model). We estimate the hourly compensation for the time required to create and update instructional material is \$35.25 (U.S. Bureau of Labor Statistics, “Employer Costs for Employee Compensation,” March 2022), total compensation for all sales and office workers in goods-producing private industries: www.bls.gov/ncs/). Therefore, the estimated annual cost to industry associated with the instructional material requirements is \$60,912 (\$35.25 per hour \times 1,728 hours). There are no operating, maintenance, or capital costs associated with the collection.

Based on this analysis, the proposed standard for APBRs would impose a burden to industry of 2,304 hours, at an estimated cost of \$81,216 annually (\$20,304 + \$60,912). Existing APBR entities would incur these costs in the first year following the proposed rule’s effective date. In subsequent years, costs could be less, depending on the number of new APBR models introduced by existing entities and/or by entities entering the APBR market. As required under the PRA (44 U.S.C. 3507(d)), CPSC has submitted the information collection requirements of this proposed rule to the OMB for review. Interested persons are requested to submit comments regarding information collection by **[insert date 30 days after date of publication in the FEDERAL REGISTER]**, to the Office of Information and Regulatory Affairs, OMB as described under the **ADDRESSES** section of this notice.

XII. Certification

Section 14(a) of the CPSA requires that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). A final rule on APBRs would subject them to this requirement.

XIII. 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.

If finalized, the Commission proposes an effective date of 30 days after publication of the final rule. 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 ASTM F3186-17 and should be ready and able to comply with the requirements included in the proposed rule. Therefore, the Commission preliminarily finds a 30-day effective date following publication of the rule in the *Federal Register* appropriate to address the risks of APBRs expeditiously. The rule would apply to all APBRs manufactured after the effective date. However, the Commission requests comments on the proposed effective date. The CPSC is not proposing an anti-stockpiling provision in the proposed rule given the brief 30-day effective time period but seeks comment on whether to include one in the final rule.

XIV. Request for Comments

We invite all interested persons to submit comments on any aspect of the proposed rule. Specifically, the Commission seeks comments on the following:

- 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;
- 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);
- 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; and
- Whether the Commission should include in the rule anti-stockpiling provisions to prevent manufacturing or importing of non-compliant APBRs at an increased rate during the period between publication of a final rule and the effective date of the rule.

XV. Notice of Opportunity for Oral Presentation

Section 9 of the CPSA requires the Commission to provide interested parties “an opportunity for oral presentation of data, views, or arguments.” 15 U.S.C. 2058(d)(2). The Commission must keep a transcript of such oral presentations. *Id.* Any person interested in making an oral presentation must contact the Commission, as described under the **DATES** and **ADDRESSES** section of this notice.

XVI. Promulgation of a Final Rule

Section 9(d)(1) of the CPSA requires the Commission to promulgate a final consumer product safety rule within 60 days of publishing a proposed rule. 15 U.S.C. 2058(d)(1). Otherwise, the Commission must withdraw the proposed rule if it determines that the rule is not reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with the product or is not in the public interest. *Id.* However, the Commission can extend the 60-day period, for good cause shown, if it publishes the reasons for doing so in the *Federal Register*. *Id.*

The Commission finds that there is good cause to extend the 60-day period for this rulemaking. Under both the APA and the CPSA, the Commission must provide an opportunity for interested parties to submit written comments on a proposed rule. 5 U.S.C. 553; 15 U.S.C. 2058(d)(2). The Commission is providing 60 days for interested parties to submit written comments. A shorter comment period may limit the quality and utility of information CPSC receives in comments, particularly for areas where it seeks data and other detailed information that may take time for commenters to compile. Additionally, the CPSA requires the Commission to provide interested parties with an opportunity to make oral presentations of data, views, or arguments. 15 U.S.C. 2058. This requires time for the Commission to arrange a public meeting for this purpose and provide notice to interested parties in advance of that meeting, if any interested party requests the opportunity to present such comments. After receiving written and oral comments, CPSC staff must have time to review and evaluate those comments.

These factors make it impractical for the Commission to issue a final rule within 60 days of this proposed rule. Moreover, issuing a final rule within 60 days of the NPR may limit commenters' ability to provide useful input on the rule, and CPSC's ability to evaluate and take that information into consideration in developing a final rule. Accordingly, the Commission finds

that there is good cause to extend the 60-day period for promulgating the final rule after publication of the proposed rule.

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 this preamble, the Commission proposes to amend 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.

1270.1 Scope, application, and effective date.

1270.2 Requirements for adult portable bed rails.

1270.3 Findings

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 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 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.

(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.

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

(i) 6.1.3 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) 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.

(ii) [Reserved]

(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 § 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.

(ii) [Reserved]

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

(i) 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).

(ii) [Reserved]

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

(i) 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.

(ii) [Reserved]

(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 6.1–6.4.

(ii) [Reserved]

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

(i) 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. 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.

(ii) [Reserved]

(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.

(ii) [Reserved]

(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.

(ii) [Reserved]

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

(i) 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.

(ii) [Reserved]

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

(i) 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.

(ii) [Reserved]

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

(i) 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.

(ii) 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.

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

(i) 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 4a, 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 4b, the space fails the test.

Figure 4 Zone 3 test: (a) Pass, (b) Fail

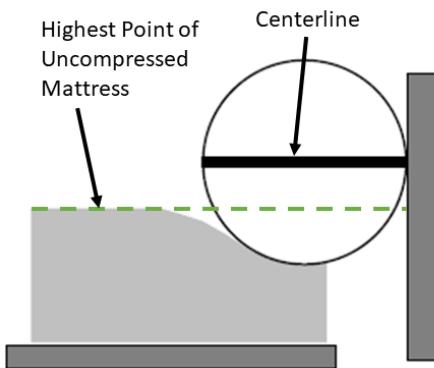


Figure 4a: Zone 3 Pass Criteria
(Centerline **above** highest point of uncompressed mattress)

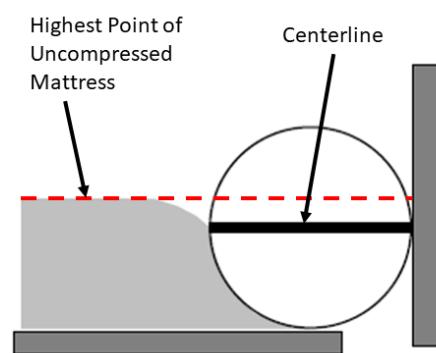


Figure 4b: Zone 3 Fail Criteria
(Centerline **below** highest point of uncompressed mattress)

(ii) [Reserved]

(15) 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.

(ii) [Reserved]

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

(i) 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).

(ii) [Reserved]

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

(i) 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.

(ii) [Reserved]

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

(i) 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.

(ii) [Reserved]

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

(i) 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.

(ii) [Reserved]

§ 1270.3 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 preliminary support for those findings.

(b) *Degree and Nature of the Risk of Injury*

Between January 2003 and December 2021, the Consumer Product Safety Risk Management System (CPSRMS) injury cases showed there were 332 incident reports concerning adult portable bed rails (APBR). Of these, 310 were reports of fatalities, and 22 were nonfatal. Rail entrapment is the most prevalent hazard pattern among the incidents, accounting for more than 90 percent of all fatal incidents. There were 284 fatal incidents related to rail entrapment. Falls were the second most common hazard pattern in the incident data, accounting for 25 incidents (8 percent). There were 23 fatalities from falls. Most of the incidents were identified from death certificates, medical examiner reports, or coroner reports. Because death certificate data often have a lag time of around two to three years from the date of reporting to CPSC, data collection is ongoing and incidents for 2020, 2021, and 2022 are likely to increase.

(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. The market for APBRs is expected to grow at an average rate of 2.01 percent per year between 2024 and 2053 as a result of an aging U.S. population seeking to avoid institutional medical care. Without a mandatory standard, assuming the rates of incidents,

per million APBRs, stay constant, this growth in the industry would lead to an average of 32 entrapment deaths per year.

(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, as well as the cost of producing the redesigned APBR. Manufacturers would likely incur expenditures in design labor, design production, design validation, and compliance testing. Manufacturers would also be required to upgrade all new APBR designs. CPSC estimates these costs to be \$42,239 per model in the first year. Once existing models have been redesigned with a working solution, however, new models can adapt at a minimal cost. Manufacturers can transfer some, or all, of the increased production cost to consumers through price increases. 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. 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 would now probably be excluded from the market because the increased market price exceeds their personal price threshold for purchasing an APBR.

(e) Any Means to Achieve the Objective of the Proposed Rule, While Minimizing Adverse Effects on Competition and Manufacturing. (1) The proposed requirement of the rule achieves the objective of reducing entrapment hazards on APBRs while minimizing the effect on competition and manufacturing. Because the proposed rule is based on an existing voluntary standard, and because of CPSC's outreach efforts, APBR manufacturers are generally aware of the requirements. The proposed rule would apply to all manufacturers and importers of APBRs.

Manufacturers can transfer some, or all, of the increased production cost to consumers through price increases.

(2) The Commission considered alternatives to the proposed rule to minimize impacts on competition and manufacturing including (1) take no regulatory action; (2) conduct a recall of APBRs instead of promulgating a final rule; (3) conduct an educational campaign; (4) require enhanced safety warnings; and (5) longer effective date. However, the Commission determines preliminarily that none of these alternatives would adequately reduce the risk of deaths and injuries associated with APBR entrapment that the proposed rule addresses.

(f) Unreasonable Risk. Incident data show 284 fatal incidents related to rail entrapment. This hazard pattern is the most prevalent among the APBR incidents, accounting for more than 90 percent of all fatal incidents. There were also 23 fatalities related to falls. 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 APBRs is forecast to grow. The proposed mandatory standard would establish performance requirements to address the risk of entrapments associated with APBRs. Given the fatal and serious injuries associated with entrapments on APBRs, the Commission preliminarily finds that this rule is necessary to address the unreasonable risk of injury associated with APBR entrapments.

(g) Public Interest

The proposed rule is intended to address an unreasonable risk of entrapments associated with APBRs. Adherence to the requirements of the proposed rule would reduce deaths and injuries from APBR entrapment incidents; thus, the rule is in the public interest.

(h) Voluntary Standards

Under section 9(f)(3)(D) of the CPSA, 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 preliminarily determines that, absent modification, the voluntary standard is not likely to eliminate or adequately reduce the risk of injury of entrapments on APBRs. The Commission also preliminarily determines that ASTM F3186-17, *see* § 1270.2, with modifications, 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. These zones were identified by the FDA in its 2006 guidance document, Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment (FDA, 2006) and used in the voluntary standard, as potential areas of entrapment for 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. The voluntary standard specifies the FDA probe 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. The four entrapment zones required to be tested 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. 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.

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.

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

(3) The Commission preliminarily 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 of market compliance testing, 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 and all products failed the labeling, warning, and instructional requirements.

(i) Reasonable Relationship of Benefits to Costs (1) The benefits expected from the proposed rule bear a reasonable relationship to its cost. The proposed rule is intended to reduce the entrapment hazards associated with APBRs, and thereby reduce the societal costs of the resulting injuries and deaths. CPSC assumes that the number of firms and APBR 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 year between 2024 and 2053 as a result of an aging U.S. population. Assuming the rates 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 value of a statistical life (VSL) of \$10.5 million (2021 dollars), the annualized present value of the potential benefits of the proposed rule therefore is \$298.11 million.

(2) The requirements of the proposed rule, with modifications, are expected to address 92 percent of deaths caused by entrapment. Benefits were assessed under three more conservative scenarios derived from this baseline efficacy, estimating benefits at: 75 percent, 50 percent, and 25 percent of their potential value. Even under the most conservative assumption that only one quarter, or 25 percent of the potential benefits are achieved, the net benefits greatly exceed the costs of the rule. The annualized benefits of the proposed rule are estimated as follows: at 75 percent - \$200.24 million, 50 percent-\$133.49 million, and 25 percent-\$66.75 million, respectively. The estimated annualized costs associated with the proposed requirements to prevent APBR hazards is \$2.01 million. This results in net quantifiable net benefits of \$198.23 million, \$131.48 million, and \$64.74 million on an annualized basis. On a per product basis, the benefits of the proposed rule are estimated between \$331.78 per APBR (75%), \$221.19 (50%), and \$110.59 per APBR (25%), and the costs are \$3.34 per APBR. All these amounts are in 2021 dollars using a discount rate of 3 percent.

(3) Injuries from entrapment and other hazards on APBRs are not included in the benefit-cost assessment because for many incidents involving injuries, there is not sufficient information to determine whether they would fall under the scope of this proposed rule. However, the injuries are quantified in a sensitivity analysis as a potential upper limit to assess the benefits of this

proposed rule. The sensitivity analysis used NEISS incidents and the Injury Cost Model (ICM) to extrapolate and generate national estimates for injuries from entrapment treated in an ED or other settings. The ICM calculated that the aggregate number of nonfatal injuries in the United States from entrapment from 2010 to 2019 was 125,121. Staff estimated that from the total of these injuries, 79,563 were treated in an outpatient setting (e.g., doctor's office or clinic), 39,149 resulted in ED treatment, and 6,409 resulted in hospital admissions.

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

The Commission considered six alternatives to the proposed rule including: (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) longer effective date. Although most of these alternatives may be a less burdensome alternative to the proposed rule, the Commission determines preliminarily that none of the less burdensome alternatives would adequately reduce the risk of deaths and injuries associated with APBRs that is addressed in the proposed rule.

Alberta E. Mills,
Secretary, Consumer Product Safety Commission



United States
Consumer Product Safety Commission

Staff Draft Notice of Proposed Rulemaking for Adult Portable Bed Rails

Petition CP 13-1, Petition Requesting a Ban or
Standard on Adult Portable Bed Rails

September 21, 2022

For additional information, contact:

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*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 notice of proposed rulemaking (NPR) briefing package in response to CP 13-1, *Petition Requesting a Ban or Standard for Adult Portable Bed Rails* (Petition). Consistent with section 9 of the Consumer Product Safety Act (CPSA), this briefing package includes an update to staff's previously reported adult portable bed rail (APBR) technical data, a preliminary regulatory analysis for APBRs, proposed language to modify and adopt ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*, into a regulation, and staff's review of the requirements of the Regulatory Flexibility Act.

Background

The Petition was docketed on June 4, 2013, based on two requests sent to the U.S. Consumer Product Safety Commission (CPSC, or Commission) from several consumer advocates on April 25, 2013, and May 9, 2013, regarding Adult Portable Bed Rails (APBRs). The Petition requested that CPSC consider rulemaking under sections 8 or 9 of the CPSA to address hazards associated with APBRs, such as entrapments, strangulations, and falls. Staff independently verified the reported hazard modes and then worked with ASTM International to develop an applicable APBR standard, which was published in 2017 as ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*.

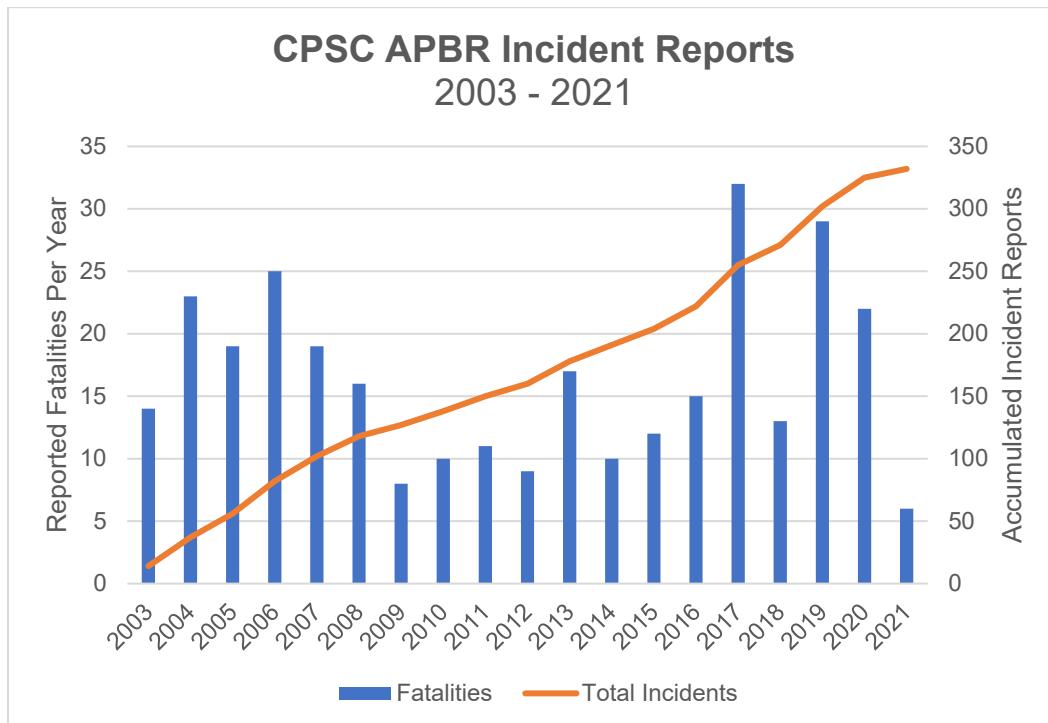
Staff evaluated whether ASTM F3186 – 17 would eliminate or adequately reduce the risk of injury posed by APBRs, by comparing the hazard patterns in the incident data to the hazards addressed by the standard. Staff also assessed if there would be substantial compliance with the standard, by collecting a substantial market sample to test to the standard's requirements. Staff's analysis indicated that the standard, with modifications, would adequately address the associated hazards, but staff did not find substantial compliance with the standard.

On March 9, 2022, staff provided their recommendation regarding the Petition in a briefing package to the Commission that also provided updates to the injury and market data to identify any changes in the market since last reported in a previous briefing package on July 15, 2020. Staff concluded that even though the voluntary standard had been in existence for 5 years, and despite staff's repeated outreach efforts to industry regarding their noncompliance with the standard, substantial compliance with the voluntary standard does not exist and will not be likely in the future, and staff recommended that the Commission grant the Petition.

On March 15, 2022, the Commission voted unanimously (4-0) to grant the Petition and directed staff to develop a draft NPR.

Economic Analysis

Most victims affected by hazardous APBRs are members of vulnerable populations, including the elderly and people with medical conditions. Annually, there are approximately 17 fatalities and over 12,000 nonfatal injuries related to APBR entrapments and strangulations. The graph below summarizes incident reports by year, from 2003 to 2021, received directly by CPSC. CPSC data collection is ongoing and it should be noted that numbers may increase for the latest 3 years due to reporting delays.



Staff's economic findings indicated the potential benefits, in the form of reduced fatalities associated with APBR use, from adopting a regulation requiring APBRs comply with ASTM F3186 – 17, with modifications, to have an annualized present value of \$298.11 million. Annualized costs associated with the proposed requirements to prevent APBR hazards were \$2.01 million. At a pessimistic 25 percent efficacy rate, the rate at which the proposed rule mitigates deaths associated with APBR use, 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, staff concludes that the potential benefits of the proposed rule significantly outweigh the potential costs.

Staff Recommendation

To prevent additional deaths, injuries, and costs to society, staff recommends that the Commission publish in the *Federal Register* an NPR under section 9 of the CPSA, soliciting comments on all aspects of the NPR, including:

- the utility of the product and consumers' needs for such products for home care, or the impact on consumers if the product was banned (e.g., lost consumer utility from not having the product);
- whether different or additional performance requirements are needed given known hazards due to variability on mattress sizes and misinstallation;
- the proposal to adopt the requirements and test methodologies of ASTM F3186 – 17, with the modifications described, into a regulation.
- stockpiling and supply chain information required to comply with a mandatory rule.

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Briefing Memorandum

Memorandum

TO: The Commission
 Alberta Mills, Secretary

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: Staff Draft Notice of Proposed Rulemaking 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*. The Commission directed staff to draft a notice of proposed rulemaking (NPR).^{1, 2}

In this draft NPR briefing package, staff recommends that the Commission submit an NPR to the *Federal Register*, requesting comments on a proposal to codify the voluntary standard ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*, with modifications, to address injuries and fatal entrapment incidents associated with adult portable bed rails (APBRs).³

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_HbfOuxiePTbEcrYMRi2hgoUczh

³ ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*, ASTM International, West Conshohocken, PA, 2017, www.astm.org.

Background

APBR Product Description^{4, 5}

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 Generally, bed rails within 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.

Figure 1 below shows four exemplar bed rail types under CPSC authority.



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

⁴ Staff's April 23, 2014 briefing package provides additional in-depth information on the jurisdiction and types of bed rails.

⁵ 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.

⁶ Information on adult bed rails under FDA jurisdiction is available at: <https://www.fda.gov/medical-devices/bed-rail-safety/safety-concerns-about-bed-rails>.

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 or 9 of the CPSA to address reported hazards associated with APBRs. The 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.^{7, 8} On April 23, 2014, CPSC staff delivered 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 again, on April 28, 2015, the Commission voted to defer the Petition in favor of allowing staff to continue assisting in developing the voluntary standard.

In August 2017, ASTM published the voluntary standard, ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. Staff updated the Commission on July 18, 2018, regarding the progress responding to the Petition. Staff's update to the Commission on July 15, 2020, assessed ASTM F3186 – 17 in light of the factors the Commission considers when granting or denying a petition.⁹

Under section 9(i) of the CPSA, 15 U.S.C. § 2058(i), the Commission may not deny a petition based on a voluntary standard, unless:

- the voluntary standard is in existence at the time of the denial of the petition,
- the Commission has determined that the voluntary standard is likely to result in the elimination or adequate reduction of the risk of injury identified in the petition, and
- it is likely that there will be substantial compliance with the standard.

Staff evaluated whether ASTM F3186 – 17 would likely eliminate or adequately reduce the risk of injury identified related to APBRs and whether there would be substantial compliance with the standard. Although staff determined that the standard, with modifications, would adequately address the associated hazards, staff did not find substantial compliance with the standard. Staff concluded that an additional round of testing would be required to assess whether substantial compliance would be likely in the future,

⁷ 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).

⁸ 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 (*i.e.*, nursing home, long-term care facility, or residence).

⁹ 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%20Petition%20CP%2013-1%20-20Requesting%20a%20Ban%20or%20Mandatory%20Standard%20on%20Adult%20Portable%20Bed%20Rails.pdf?kiDixW5Z7x9xcOqjxSeS3QpvspdfQMBY>

as required by the CPSA.¹⁰ To promote compliance during this time, 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.¹¹

Staff's briefing package dated March 9, 2022, provided updates to the injury and market data previously reported to identify any changes in the market since it was reviewed in 2018.¹² Despite the additional outreach and time for manufacturers to adopt the voluntary standard, staff did not find substantial compliance with the 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).

Incident Data & Hazard Analysis^{13, 14, 15}

In preparing the draft NPR, CPSC staff from the Hazard Analysis Division of the Directorate for Epidemiology (EPHA) summarized the data on deaths and injuries involving APBRs. Staff from the Directorate for Health Sciences (HS) and from the Human Factors Division of the Directorate for Engineering Sciences (ESHF) reviewed these data and the reported incidents involved to develop an analysis on the affected population and define the hazard modes associated with incidents involving APBRs.

¹⁰ 15 U.S.C. § 2058(i).

¹¹ 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>.

¹² 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>

¹³ 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.

¹⁴ 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.

¹⁵ 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)¹⁶
 - Data spanned from January 1, 2003, through December 31, 2021. Data collection is ongoing in CPSRMS, and reporting is considered incomplete for the latest 3 years.
- The National Electronic Injury Surveillance System (NEISS)¹⁷
 - NEISS-based injury estimates are from January 1, 2003, to December 31, 2021; finalized NEISS data and estimates for 2022 will be available in spring 2023.

CPSRMS Incident Data Summary

Between January 2003 and April 2022, CPSC received 332 incident reports related to APBRs, that occurred 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 newspaper clippings, consumer reports, and retailers/manufacturers. Staff organized the data by age, gender, location, and underlying medical condition.

Victims' ages ranged from 14 to 103 years old. More than 75 percent of the incident victims were age 70 or older, and almost 80 percent of the reported fatalities involved victims ages 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.

¹⁶ The most recent search of the CPSC databases for adult portable bed rail incidents 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.

¹⁷ 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 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, for example. 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.

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	10	0	10
Cancer	7	0	7
Cerebral palsy	6	0	6
Multiple sclerosis	5	0	5
Other*	20	0	20
Unknown/Not Reported	123	21	144

Source: CPSRMS (2003-2021).

*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.

**Table 4 sums to more than 332 due to multiple conditions reported

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 reports this data by year.

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

Year	Estimate ¹⁸	Sample Size	Injury Rate ¹⁹
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: NEISS (2003-2021).

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

Hazard Analysis

Staff reviewed the 332 CPSRMS APBR-related incident reports (e.g., death certificates, medical examiner reports, coroner reports) to identify all relevant hazard patterns.

Rail Entrapments

The most common hazard pattern among all reported incidents is rail entrapment, accounting for more than 90 percent or 284 of 310 of the fatal incidents. Rail entrapment incidents include cases 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 also 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, and results in strangulation. Blood vessels delivering oxygen to the brain in the neck 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.

¹⁸ 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.

¹⁹ 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 \(census.gov\)](https://www.census.gov)

Falls

Staff identified falls as the second most common hazard pattern associated with APBRs, accounting for 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.

Incident Data & Hazard Analysis Staff's Conclusion

Staff found that the vast majority of incident victims in CPSRMS were members of vulnerable populations.

- Elderly
 - More than 75 percent of the victims were age 70 or older.
 - More than 80 percent of the reported fatalities involved victims ages 70 or older.
- Persons affected by medical conditions
 - 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 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^{5, 20}

Prior to the development of ASTM F3186 – 17, in accordance section 9(i) of the CPSA, 15 U.S.C. § 2058(i), 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 due to jurisdictional differences, this guidance document was not considered applicable for consumer products that are not medical devices.

For this briefing package, staff conducted an additional search for applicable standards in 2022, but they found no relevant standard, other than ASTM F3186 – 17.²¹

Staff's Analysis of ASTM F3186 – 17^{3, 9, 9, 12}

Pursuant to section 9(i) of the CPSA, 15 U.S.C. § 2058(i), staff reviewed the requirements of ASTM F3186 – 17 and concluded that, with some modifications, the voluntary standard would adequately address the identified hazard patterns related to APBRs. The sections below summarize the staff's previous analysis of the requirements.

Scope and Definition

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

²⁰ 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

²¹ 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.

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.

Staff worked with the ASTM subcommittee to develop these definitions based on the scope of the Petition and the types of portable bed rails that are not covered by CPSC’s existing regulations for children’s bed rails. 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.

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. Section 5.3 requires that products covered by the standard that are installed on a bed that articulates (*i.e.*, is adjustable) must meet the performance requirements when the bed is in the flat and articulated positions.

General requirements mandating smooth edges on exposed parts improve safety by preventing potential lacerations or skin injuries from APBRs. In addition, staff finds that testing APBR products on articulating beds is essential to assess openings that could potentially lead to entrapment when the bed is adjusted from the flat position to the articulated position.

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.

Misassembly and Misinstallation

Staff identified 284 fatal incidents related to rail entrapment. This hazard pattern is the most prevalent among the incidents, accounting for more than 90 percent of all fatal incidents. 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 call for the product to be tested without 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.

Staff concluded 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. However, staff recommends asking for comment on whether this sufficiently reduces the risk, or if other measures, up to and including a ban, are needed.

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 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 minority of fall-related incidents, according to staff's review, involved the victim deliberately climbing over the APBR. Section 6.2 of ASTM F3186 – 17 also 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, particularly consumers who deliberately climb over APBRs.

Entrapment Testing

Staff identified entrapment as the most prevalent hazard pattern among the incidents. In accordance with the entrapment test methods specified in Section 8 of the standard, 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. 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.^{22, 23} ASTM F3186-17 specifies the FDA probe 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. Staff determined in the July 15, 2020 Staff Briefing Package that the performance requirements in the standard, including testing entrapment zones using the FDA entrapment test probe, should effectively address the entrapment hazard posed by a properly installed APBR.

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 zones require 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.

Table 6: ASTM F3186 – 17 Entrapment Zones

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

²² 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.

²³ 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.

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.

Table 7: 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 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 also directly used in the entrapment requirements of ASTM F3186 – 17.

Staff concludes that compliance with the entrapment requirements, based on identified entrapment patterns and related anthropometric data, could adequately address the identified entrapment hazard patterns related to 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. The space between the APBR and head board or foot board is considered Zone 6 in relation to the 2006 FDA guidance document. ASTM F3186 – 17 requires the consumer to correctly install the APBR at the specified distance from the headboard or foot board 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 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 design.

Staff's Assessment of ASTM F3186 – 17 Performance Requirements

Staff's previous briefing package concluded that compliance with the requirements of the standard could adequately reduce the risk of injury from hazards associated with APBR products.^{9, 12} Although staff found that the standard would adequately address the risk of injuries and fatalities associated with APBRs, staff also identified some areas of the standard that must be improved upon, such as corrections to the requirements for labels and warnings, and several corrections and clarifications for certain test procedures. Staff has continued to work with ASTM to refine these parts of the standard.²⁴ Staff's updated incident data, included in this briefing package, indicate that the previously identified hazard patterns continue to occur because manufacturers currently do not comply with the voluntary standard, as discussed below.

Staff's Assessment of Market Compliance to ASTM F3186 – 17^{20, 25}

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 of market compliance testing, no products 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 the sections above, an APBR that fails any one mechanical performance requirement could result in a fatal entrapment or other known hazard. Furthermore, all products failed the labeling, warning, and instructional requirements. In this section staff summarizes:

- Staff's 2018 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

From 2018 through 2019, CPSC staff tested 35 randomly selected APBR models for compliance with ASTM F3186 – 17, which became effective in August 2017. APBRs 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 requirements and the performance requirements of the standard. ESHF staff tested conformance with the labeling, warning, and instructional literature

²⁴ Staff Correspondence Relating to Voluntary Standards, *CPSC Letter to ASTM F15.70 – F3186 Proposed Language*, June 10, 2022. Retrieved from: https://www.cpsc.gov/s3fs-public/APBRCPSCLettertoASTMF1570F3186ProposedLanguage_20220610.pdf

²⁵ 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.

requirements. Staff found that none of the 35 sampled products conformed to the voluntary standard. Staff concluded that market compliance with the standard was likely low when staff purchased the samples in 2018, after the standard had become effective. However, due to the lack of proper labeling, staff could not confirm all the manufacture dates for the products to compare them to the standard's effective date. As shown in Table 8 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 8: ASTM F3186 – 17, 2018 APBR Market Compliance Testing Result Summary

Section		Title	# of Failed Samples	Failure Rate (of 35 Total Samples Tested)
			(of 35 Total Samples Tested)	
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 among the reported incidents identified in the 2020 briefing package, accounting for 226 of the 260 incidents. 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.

Staff's testing also revealed high failure rates in several other sections, 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, 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.²⁶

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 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.²⁷

Market Outreach (2020 to 2021)

To promote market awareness of the standard and associated hazards, staff conducted outreach through CPSC's Office of Compliance and Field Operations (Compliance). In June 2020, Compliance sent a letter to 19 known APBR manufacturers, urging industry members to ensure that their APBRs comply with ASTM F3186 – 17. 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 has continued 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 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, and participated as technical experts at all subcommittee task groups.

2021 APBR 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 since 2018 was sufficient for manufacturers to increase their overall level of compliance to the standard. A representative 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 remaining available market. The nine randomly selected models were products previously identified in the 2018 analysis, which were included to account for any undisclosed changes to the models that may have improved their compliance to the voluntary standard.

²⁶ 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.

²⁷ 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

The 2021 testing, like the 2018 analysis, was designed to assess 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 these performance requirements. Detailed testing results are provided in Appendix B.²⁸

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 also similar to the results of the 2018 analysis, indicating little-to-no changes in the market over this time.

Table 9: 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

CPSC has issued five public notices regarding 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.²⁹ The firm is now out of business. Bed Handles, Inc., manufactured approximately 193,000 units of the bed rails, and CPSC is aware of four entrapment deaths associated with them.

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:

²⁸ 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.

²⁹ 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>.

- Drive DeVilbiss Healthcare (496,100 units, 2 deaths);³⁰
- Compass Health Brands (104,900 units, 3 deaths); and³¹
- Essential Medical Supply, Inc. (272,000 units, 1 death).³²

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 model have occurred.³³ Mobility Transfer Systems, Inc., is no longer in business, and neither firm has agreed to conduct a recall. Approximately 285,000 units were manufactured.

APBR Market Compliance Testing Staff Conclusion

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

Proposed Requirements for a Mandatory Safety Standard for APBRs ^{12, 22, 24, 26, 34}

Staff is actively participating in the F15.70 subcommittee to encourage further voluntary development of the standard and has been for years. Staff are members of the revision task group for ASTM F3186 – 17, which has been reviewing the standard and developing new language to improve the standard for its next revision.

Based on staff's incident analysis and staff's assessment of ASTM F3186 – 17 above, compliance to the voluntary standard, with some modifications for improved clarity and effectiveness, would likely address all known product hazard modes associated with APBRs. Staff recommends adopting ASTM F3186 – 17 with the modifications listed in the following section into a mandatory product safety standard.

Given firms familiarity with ASTM F3186-17 and knowledge of CPSC regulatory activity, firms should be able to quickly comply with the requirements included in the draft proposed rule. Therefore, staff recommends an effective date 30-days following publication of the rule in the *Federal Register*. Per this 30-day effective date, no stockpiling requirements are included in the draft proposed rule.

³⁰ PR #22-025, <https://www.cpsc.gov/Recalls/2022/Drive-DeVilbiss-Healthcare-Recalls-Adult-Portable-Bed-Rails-After-Two-Deaths-Entrapment-and-Asphyxiation-Hazards>.

³¹ 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>.

³² 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>.

³³ 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>.

³⁴ 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.

Staff's Recommended Modifications to ASTM F3186 – 17

Staff concludes that the standard will be effective in addressing the hazards if the following proposed modifications to ASTM F3186 – 17 are adopted, to clarify certain sections and improve safety, including:

- Providing additional definitions for “product assembly and installation” to ensure their consistent and differentiated use throughout the document.
- Including requirements for manufacturers to inform the consumer of the range of mattress thicknesses, to ensure safe use of the product and provide testers with guidance for selecting the mattress thickness during the test setup.
- Addressing inconsistencies with stated dimensions to ensure consistent dimensional tolerances.
- Updating the requirements for Zone 3 testing to be consistent.
- Providing additional clarity for Zone 1 and 2 test setup and methods. Additional guidance is also provided for identifying potential Zone 2 openings.

Additional information on these modifications is listed below and in Tab F of this briefing package.³⁵

Proposed Redline Modifications to ASTM F3186 – 17

The proposed changes to the standard are listed below. Modifications are shown in red. Underlined sections are to be added, and sections that are struck through are to be removed. Staff's rationale for these modifications is provided below each set of proposals.

Proposals for Additional Definitions and Revisions for Related sections

The following definitions should be added to the standard to improve the clarity of the requirements that use them:

Proposed § 3.1.8: *Initial Assembly*, n— the first assembly of the product components after purchase, and prior to installing on the bed.

Proposed § 3.1.9: *Initial Installation*, n— 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).

Proposed § 3.1.10: *Installation Component*, n— component(s) of the bed rail that is/are specifically designed to attach to the bed rail to 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).

In conjunction with the proposed definitions, sections 6.1.3 and 9.2.7 should be updated accordingly.

³⁵ The proposed redline modifications to ASTM F3186 – 17 in this briefing memo organize staff's proposed modifications by relative type. The version of the redline in Tab F is in sequential order as the sections appear in the standard.

Proposed § 6.1.3: Permanently attached retention system components shall not be able to be removed without the use of a tool after initial **installation 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.

Proposed § 9.2.7: At least one **conspicuous 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 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.

Proposed § 8.6.3 reference definition NOTE 5: 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. The current note numbers in the standard are redundant and should be updated. Adopting this note would make it “Note 5” and make the current Note 2, “Note 6” instead.

Proposals for Mattress Thickness Variability

Mattress thickness is a known variable that may cause some APBR product designs to have hazardous entrapment zones. Guidance on what thickness of mattress to use for testing APBR products is not adequately addressed in the current standard. The following modifications to these sections should be applied globally to all related testing to address this issue.

Proposed Global Requirement and § 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 shall be applied in addition to those requirements.

Proposed Global Requirement and § 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.

Proposed Mattress Type Clarification: NOTE 2: 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. The current note numbers in the standard are redundant and should be updated. Adopting this note relative to section 7.1 would constitute "Note 2".

Previously Proposed Modifications to ASTM F15.70

Staff has proposed language in previous briefing packages and recent communications with ASTM F15.70 on sections 6.3.3, 8.4.5.4, and 6.4.1. Staff's proposed language is currently under review by ASTM F15.70 and may not be adopted into the voluntary standard until the subcommittee publishes a new version of the standard. Therefore, staff have included the proposed language in this section to be considered as part of the proposed mandatory standard. The following is the proposed language for each section.

Proposed § 6.3.3: Zone 3— The highest point on the cylinder of the test probe (see 7.2) shall not pass completely below the horizontal uncompressed plane of the mattress when tested according to

8.4.5. 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 7.2) shall be above the highest point of the uncompressed mattress.

Proposed § 8.4.5.4: Turn the cone until the centerline on the face of the 4.7 in (119.38 mm) end is horizontal and let the cone sink into the space by its own weight.

- (1) If the line on the face of the 4.7 in (120 mm) end of the cone is above the surface of the mattress highest point of the uncompressed mattress, as shown in Figure 4a, the space passes the test.
- (2) If the line on the face of the 4.7 in (120 mm) end of the cone is at or below the surface of the mattress highest point of the uncompressed mattress, as shown in Figure 4b, the space fails the test.

Proposed Figures for § 8.4.5.4 Reference, Figure 4a and 4b: Zone 3 test: (a) Pass, (b) Fail

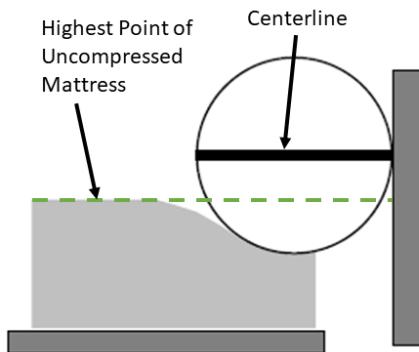


Figure 4a: Zone 3 Pass Criteria
(Centerline **above** highest point of
uncompressed mattress)

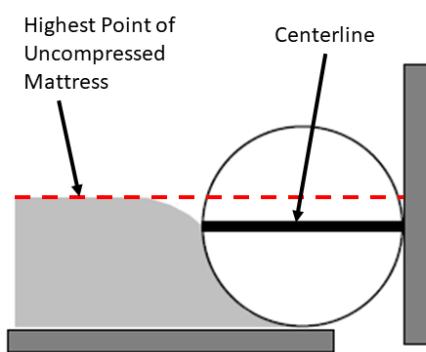


Figure 4b: Zone 3 Fail Criteria
(Centerline **below** highest point of
uncompressed mattress)

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 proposed to assist testers in visualizing the test criteria.³⁶

Proposed § 6.4.1: Holes or slots that extend entirely through a wall section of any rigid material less than 1/4 0.375 in. (6.35 9.53 mm) thick and admit a 5/8 0.210 in. (15.9 5.33 mm) diameter rod shall also admit a 1- 0.375 in. (25.4 9.53 mm) diameter rod. Holes or slots that are between 8-mm 0.210 in (5.33 mm) and 25-mm 0.375 in (9.53 mm) and have a wall thickness less than 1/4 0.375 in. (6.35 9.53 mm) but are limited in depth to 1/4 0.375 in. (6.35 9.53 mm) maximum by another rigid surface shall be permissible (see Fig. 2).

Rationale: The measurement references in 6.4.1 were not accurate or consistent with it or the referenced Figure 2. The proposed change 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).

³⁶ 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.

Clarification for Entrapment Testing Probe Pull Force Application for Entrapment Zones 1 and 2

The proper test methodology for exerting the required pull force on the test probe for entrapment zones may be unclear to those unfamiliar with the associated hazard pattern. The following modifications are proposed to make the test method clear and repeatable. The current language in section 8.4.4 for Zone 2 entrapment testing also may be interpreted in several ways. The following proposed language will help make the test method clearer and more repeatable.

Proposed § 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 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 and pass through 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.

Proposed § 8.4.4.3: Insert the 2.4-in. (60 mm) end of the cone perpendicular into the opening from the longitudinal centerline of the mattress. 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.

Proposed § 8.4.4.4: If the test probe does not pull through freely, using 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 in both directions perpendicular to the rail.

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.

Proposed § 8.4.4.5: If a horizontal section of the rail greater than 4.7 in (120 mm) exists along the bottom of the rail, that section must also meet the Zone 2 requirements.

Rationale: During the development of the APBR 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.

Other Proposed Modifications to ASTM F3186 – 17
The proposed changes below are mainly editorial in nature, but also may help to improve the clarity of the voluntary standard.

Proposed § 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 disassembly with the use of a tool is not considered as “misassembly” under section 6.5.

Proposed § 6.5.2: Determining Misassembled Product: A product covered by this specification shall be considered misassembled 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.

Proposed § 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:

<http://www.fda.gov/MedicalDeviceRegulationandGuidance/GuidanceDocuments/ucm072662>.
<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 it can be purchased from NST Sales & Customer Service Office, 5154 Enterprise Blvd., Toledo, Ohio 43612, 800-678-7072, www.nst-usa.com. A video illustrating use of the test probe is available at the NST website (free registration required).

Rationale: Editorial change, the previous hyperlink and business contact information were out of date. The updated company information is as follows: Bionix Development Corporation, 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>”.

Proposed NOTE 43: The tests described in this section are identical similar to those described in the referenced FDA Guidance Document and in the NSA video.

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. The

current note numbers in the standard are redundant and should be updated. This note number was changed to 3 to align with other proposed changes.

Proposed § 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 ~~either <2.4 in. (60 mm) or >12.5 in.~~ (318 mm).

Rationale: This 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 revision task group has agreed to these changes, and they will be incorporated into the next revision of the standard.

Proposed § 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, ~~and~~ 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 a grammatical edit and brings the warning language into alignment with similar language used in Section 9.2.6.

Proposed § 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 to include "its."

Economic Analysis for the Proposed Rule on Adult Portable Bed Rails^{37, 38}

CPSC staff from the Directorate for Economic Analysis (EC) developed a Preliminary Regulatory Analysis, and an Initial Regulatory Flexibility Analysis included in this NPR.

Pursuant to section 9(c) of the CPSA, publication of a proposed rule must include a preliminary regulatory analysis containing the following:

- (1) a preliminary description of the potential benefits and costs of the proposed 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;

³⁷ Tab G, Row, R. Memorandum by The Directorate for Economic Analysis, *Adult Portable Bed Rail Preliminary Regulatory Analysis*, 2022.

³⁸ Tab H, Row, R. Memorandum by The Directorate for Economic Analysis, *Adult Portable Bed Rail Initial Regulatory Flexibility Analysis*, 2022.

- (2) a discussion of the reasons why a standard submitted to the Commission was not published as the proposed rule;
- (3) a discussion of why a relevant voluntary safety standard would not eliminate or adequately reduce the risk of injury addressed by the proposed rule; and
- (4) a description of any reasonable alternatives to the proposed rule, together with a summary description of their potential costs and benefits and why such alternatives should not be published as a proposed rule.

This section summarizes the information required in the Preliminary Regulatory Analysis and Initial Regulatory Flexibility Analysis included in this NPR.

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, this suggests the number of APBRs sold annually is between 40,000 and 182,000 units. Based on an interview with an APBR manufacturer's representative, the higher end of these sales ranges is considered more likely \$9 million and 180,000 units.

Analysis of Potential Benefits and Costs

Benefit Analysis

To determine the potential benefit that may be gained by adopting the proposed rule, staff calculated the reduction in societal costs, by estimating the number of deaths from entrapment and strangulation that would be prevented through market compliance to the proposed rule. Staff did not include injuries in its benefit-cost assessment because, for many of these incidents, there is not enough information to determine whether they would fall within the scope of this draft proposed rule. Staff was unable to determine if the injury was caused by an APBR or some other type of bed rail. Also, staff was unable to determine a specific cause of the injury. However, staff does quantify and monetize the injuries in a sensitivity analysis in section 5 of Tab G as a potential upper limit to the benefits of this draft proposed rule.

Staff forecasted the number of expected deaths over a 30-year period and converted the value of prevented casualties into monetary terms using the Value of Statistical Life (VSL).³⁹ Staff forecasted deaths by applying an estimated death rate per million APBRs to the estimated APBRs currently in use for each year of the 30-year period. Furthermore, staff considers the projected growth rate of the health home 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 current use, and subsequently, deaths from those APBRs.

To estimate the societal costs of entrapment and strangulation-related deaths, staff applied estimates of the VSL developed by the U.S. Environmental Protection Agency (EPA). The EPA estimate of the VSL

³⁹ 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.

inflated to 2021 dollars is \$10.5 million.⁴⁰ Staff multiplied the VSL by the 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.

The requirements of the draft proposed rule are expected to address 92 percent of deaths caused by entrapment and strangulation if the APBRs operate as expected. However, the effectiveness of the draft proposed rule depends, to some extent, on consumers installing the product correctly. The draft proposed rule provides significant improvements designed to help consumers; however, there may still be some injuries and deaths resulting from improper installation 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 proposed rule. Therefore, to assess potential benefits, CPSC considers three scenarios: 75 percent, 50 percent, and 25 percent of achievable benefit amounts. Staff chose these levels as a stress test for the draft proposed rule to see how its benefits compared, even under the pessimistic assumption of a 25 percent rate. CPSC staff estimates the annualized benefits of the draft proposed rule under these three scenarios, assuming an annual discount rate of 3 percent, to be \$200.24 million, \$133.49 million, and \$66.75 million, respectively.

Cost Analysis

Like the benefits estimation, 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.⁴¹ Staff considers a single, feasible solution for the cost analysis, which requires manufacturers to fully redesign their APBR models to comply with ASTM F3186 – 17, with proposed modifications. Staff assumes that 100 percent of manufacturers will adopt the proposed solution and staff estimated the cost of the draft proposed 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 APBR.⁴² The increased manufacturing cost may then be passed on, at least in part, to wholesalers, retailers, and consumers. The subcategories of costs for implementing a solution to the APBR entrapment and strangulation hazard are detailed below.

Cost of Redesigning Existing APBR Models and New Designs on Manufacturers

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

- Cost of Design Labor
- Cost of Design Production

⁴⁰ In 2008, the EPA estimated the value of a 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 to the nearest hundred thousand. The adjustment is as follows: $\$7.9M \times (278.802/210.228) = \$10.477M$, which is then rounded to \$10.5M.

⁴¹ 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.

⁴² The draft proposed rule does not require manufacturers to update or replace APBRs manufactured or sold before implementation of the proposed APBR mandatory standards.

- 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 1 month to produce a final blueprint of an APBR model design that complies with the requirements of the draft proposed rule, or approximately a total of 347 hours.⁴³ 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.⁴⁴

Cost of Design Production

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

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.⁴⁵

⁴³ 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).

⁴⁴ 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>).

⁴⁵ Subject matter expert input was \$20,000 in 2020 dollars. Staff inflated to 2021 dollars using the Consumer Product Index (CPI-U).

Cost of Compliance Testing

This expense covers the cost of conducting formal, third party compliance testing to verify compliance with the requirements of the new APBR mandatory standards. Compliance testing is customarily conducted through third party testing.

Staff estimated that, on average, four APBR models would be tested per day, or \$5,356 per redesigned model.⁴⁶

Cost of Manufacturing the Redesigned APBR

Manufacturers incur costs to produce redesigned APBRs after implementation of the draft proposed rule.⁴⁷ 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 proposed rule.

Dead Weight Loss

Dead weight loss (DWL) refers to the lost producer and consumer surplus due to reduced quantities sold and consumed following price increases resulting from the proposed 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 proposed rule to be \$68,944 per year, or approximately \$2.07 million, \$1.23 million in present value, over the 30-year study period.

Cost of CPSC Oversight

Staff does not expect the implementation of the proposed rule to require significant resources or additional oversight and compliance monitoring by CPSC. CPSC can reasonably 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 Adult Portable Bed Rails for the Draft Proposed 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 \$64.74 million for these scenarios. Expressed another way, over the 30-year study period, staff found that for each \$1 in cost from the draft

⁴⁶ Subject matter expert input was \$5,000 in 2020 dollars. Staff inflated to 2021 dollars using the Consumer Product Index (CPI-U).

⁴⁷ The APBR can be fabricated in-house by the manufacturer or by a third-party contractor hired by the manufacturer.

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 \$328.44, \$217.85, and \$107.25 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 proposed 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 Proposed Rule

Staff considered six alternatives to the draft proposed rule: (1) Do not undertake regulatory action; (2) 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; or (6) Implement a proposed rule with a longer phased-in introduction period. Staff does not recommend these alternatives as, even if each case other than alternative (4) were implemented together, much of the societal costs associated with APBR use, in the form of fatal and nonfatal injuries, will continue to be incurred. If the Commission promulgated 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 the product that provides utility to users, may outweigh the benefit. Considering both the quantifiable and unquantifiable costs and benefits, staff determined that the net benefit of this alternative is likely less than that of the draft proposed rule. Therefore, staff does not recommend banning APBRs as an alternative action, which would 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. However, staff recommends soliciting public comments on whether ban is warranted, and if so, what the impact of a ban is on consumers, given that if not banned improperly installed APBRs could still pose hazards to consumers.

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 proposed rule exceeds 1 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 small. A small importer whose supplier exits the market or does not provide the importer a General Certificate of Conformity (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 1 percent of annual revenue. Furthermore, given the growing market, staff does not anticipate foreign manufacturers to exit the U.S. market. Moreover, staff assumes that foreign manufacturers would provide certifications that small importers could rely on, and thus, these foreign manufacturers could preserve their sales. Therefore, staff assesses the rule will not have a significant economic impact on APBR importers.

In summary, the proposed 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 the one small APBR importer.

Staff's Conclusion and Recommendations

Staff concludes that a mandatory rule would increase compliance from APBR manufacturers, and ASTM F3186 – 17, as modified above, would reduce casualties associated with APBRs.

After reviewing Petition CP 13-1, staff concluded that market compliance with a modified ASTM F3186 – 17, would substantially address the identified hazard patterns associated with virtually all APBR-related deaths and injuries. Despite staff's continued collaboration with ASTM and market outreach efforts, staff has found little to no evidence demonstrating substantial compliance with the voluntary standard since its publication in 2017. Therefore, on March 15, 2022, the Commission voted unanimously to grant Petition CP 13-1 and directed staff to develop this draft NPR.

If APBRs are left unregulated, CPSC staff estimates an average of 32 deaths related to APBR entrapments and strangulations would occur each year between 2024 through 2053. The vast majority of these victims are considered to be within vulnerable populations, including the elderly and those with medical conditions.

Staff's analysis acknowledges that adopting the proposed 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, society will achieve a monetary benefit of \$33.15 for every \$1 in costs to ensure all APBRs meet the proposed rule.

Given the market's familiarity with ASTM F3186 – 17 and knowledge of ongoing CPSC actions related to APBRs, and the disparity between the estimated costs and benefits of compliance to the proposed rule; manufacturers should comply with any rule that becomes effective relatively quickly. Therefore, staff recommends a 30-day effective date with no stockpiling provisions for the proposed rule.

Additionally, to better prevent additional deaths, injuries and costs to society, staff recommends that the Commission use section 9 of the CPSA to publish an NPR in the *Federal Register* soliciting public comments on the following:

- the utility of the product and consumers' needs for such products for home care, or the impact on consumers if the product was banned (e.g., lost consumer utility from not having the product);
- whether a product ban is warranted, due to the uncontrollable variables related to known hazards such as bedding and proper installation;
- the proposal to adopt the requirements and test methodologies of ASTM F3186 – 17, with the modifications described, into a regulation.
- stockpiling and supply chain information required to comply with a mandatory rule.

Tab A: Memorandum by The Directorate for Epidemiology, Division of Hazard Analysis



Memorandum

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

THROUGH: Stephen Hanway, Associate Executive Director,
 Directorate for Epidemiology
 Risana Chowdhury, Director,
 Division of Hazard Analysis,
 Directorate for Epidemiology

FROM: Chao Zhang, Statistician,
 Division of Hazard Analysis,
 Directorate for Epidemiology

SUBJECT: Adult Portable Bed Rail-Related Deaths, Injuries, and Potential
 Injuries¹

DATE: September 14, 2022

Introduction

The U.S. Consumer Product Safety Commission's (CPSC) Directorate for Epidemiology (EPHA), Division of Hazard Analysis, prepared this review of data and characterization of hazard patterns from deaths and injuries involving adult portable bed rails.

The reported incidents from CPSC's Consumer Product Safety Risk Management System (CPSRMS) are from January 1, 2003, through December 31, 2021. Data collection is ongoing in CPSRMS, and reporting is considered incomplete for the latest 3 years; the most recent search was conducted in April 2022.² The National Electronic Injury Surveillance System (NEISS)-based injury estimates are from January 1, 2003, to December 31, 2021; finalized NEISS data and estimates for 2022 will be available in spring 2023.

This memorandum updates the APBR briefing package³ completed in March 2022. The data search for the previous analysis was conducted in September 2021, and it covered the period of January 2003 through March 2021, for data from CPSRMS, and January 2003 through December 2020, for data from NEISS.

The ASTM International (ASTM) voluntary standard for adult portable bed rails is F3186-17, *Standard Specification for Adult Portable Bed Rails and Related Products*. According to ASTM's definition, an "adult portable bed rail" is a product that is not designed by the manufacturer as part of the bed, and it is

¹ This analysis was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission. Not all these incidents are addressable by an action the CPSC could take; however, it was not the purpose of this memorandum to evaluate the addressability of the incidents, but rather, to quantify the number of fatalities and injuries reported to CPSC staff.

² The most recent search of the CPSC databases for adult portable bed rail 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.

³ 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>

installed on, against, or adjacent to the side of an adult bed, and it is used by adults to reduce the risk of falling from the bed, to assist in repositioning in the bed, to assist in transitioning into or out of the bed, or for other similar purposes as stated by the manufacturer. Adult portable bed rails that meet the definition of a “medical device” are under the jurisdiction of the U.S. Food and Drug Administration (FDA), and adult portable bed rails that are not medical devices fall under the jurisdiction of CPSC. In this memorandum, CPSC staff limited the data to non-medical devices and incidents reporting user age to be 13 years or older. Incidents where the user’s age is unknown or unreported are also included in this memo.

Incident Data (CPSRMS)

Between January 2003 and April 2022, CPSC received reports of 332 incidents related to APBRs that occurred between January 2003 and December 2021. Of the 332 incidents, there were 310 deaths and 22 nonfatal incidents. The previous analysis completed in November 2021 for incidents between January 2003 and March 2021 found 320 total incidents, including 300 deaths and 20 nonfatal incidents. The majority of the reports received were death certificates and medical examiner/coroner reports; the remaining reports were submitted through various sources, such as newspaper clippings, consumer reports, and retailers/manufacturers.

Table 1 presents a more detailed breakdown of the severity of incidents by year. As previously mentioned, data collection is ongoing; death certificate data often have a lag time of around two to three years from date of death to date of reporting to CPSC. As the APBR data in CPSRMS is heavily reliant on death certificates, at the time of writing of this memorandum, data for 2020, 2021 and 2022 should all be considered incomplete.

Table 1: Distribution of Reported APBR-Related Incidents by Year and Severity, January 2003–December 2021

Year	Fatalities	Nonfatal Injuries	No/Unspecified Injury	Total Incidents
2003	14	0	0	14
2004	23	0	0	23
2005	19	0	0	19
2006	25	0	1	26
2007	19	0	1	20
2008	16	0	0	16
2009	8	0	1	9
2010	10	1	0	11
2011	11	1	0	12
2012	9	0	1	10
2013	17	0	1	18
2014	10	2	1	13
2015	12	0	1	13
2016	15	0	3	18
2017	32	1	0	33
2018	13	2	1	16
2019	29	2	0	31
2020	22	1	0	23
2021	6	1	0	7
Total	310	11	11	332

Source: CPSRMS (2003-2021). Data for 2020 and 2021 should be considered incomplete.

Table 2 and Table 3 detail the distribution of injuries by age and gender, respectively. The age of the victims ranged between 14 and 103 years old. Over 75 percent of the victims were aged 70 or older, and almost 80 percent of the reported fatalities involved victims ages 70 or older. Almost 70 percent of the victims were female, and around 72 percent of the reported fatalities were female. The distributions of age and gender were similar to the ones derived in the previous memorandum.

Table 2: 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 3: 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).

Table 4 provides a distribution of the incidents by injury location. Almost 50 percent of incidents (and 51 percent of fatalities) occurred at home.

Table 4: 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.

Table 5 details the most common underlying medical conditions of the victims. As outlined in Tab B, these conditions can restrict hazard awareness as well as the ability to self-rescue. Around 34 percent of incidents reported the victim to have multiple medical conditions, and around 58 percent of incidents reported at least one underlying medical condition. As some victims had more than one listed medical condition, the total number of medical conditions exceeds the total number of incidents. The vast majority of nonfatal incident reports (all reports except one) did not list any underlying medical condition.

Table 5: 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	10	0	10
Cancer	7	0	7
Cerebral palsy	6	0	6
Multiple sclerosis	5	0	5
<i>Other*</i>	20	0	20
Unknown/Not Reported	123	21	144

Source: CPSRMS (2003-2021).

*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, diabetic, sepsis, leukemia, severe disabilities, advanced age and general weakness.

The hazard types were grouped into four categories based on the bed rail's role in the incident. The hazard pattern was similar to what was presented in the last memorandum. The categories are listed in order of highest to lowest frequency.

- **Rail entrapment:** There were 286 incidents 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. This category includes 284 fatalities and two nonfatal injuries from entrapment or wedging between the bed rail and mattress.
- **Falls:** There were 25 incidents 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 bed rail, and fell after climbing over the bed rail. This category includes 23 deaths, one nonfatal knee fracture and one non-injury incident.
- **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.

National Injury Estimates (NEISS)

Between January 2003 and December 2021, there were an estimated 79,500 injuries (sample size = 1,946, coefficient of variation = 0.07) related to adult bed rail products treated in hospital emergency departments across the United States. There appeared to be a statistically significant positive trend in injuries during this period ($p = 0.047$).

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 6, 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 6: NEISS Estimates for Injuries Related to Adult Bed Rails,
January 2003–December 2021**

Year	Estimate ⁴	Sample Size	Injury Rate ⁵
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: NEISS (2003-2021).

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

Table 7 presents a breakdown of the disposition of the injured patients. The vast majority (88 percent) of patients were treated and released or examined and released without treatment, while around 11 percent were hospitalized or held for observation. There was only one NEISS case that involved a death; the remaining 1,945 cases involved nonfatal injuries. This one NEISS case involving a death is separate from any of the CPSRMS incidents, and it was also unclear what specific type of adult portable bed rail was involved.

⁴ 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.

⁵ Obtained by dividing NEISS estimates by U.S. Census Bureau population estimate for the respective year (for ages 13+). Latest data can be found here: [National Population by Characteristics: 2020-2021 \(census.gov\)](https://www.census.gov/data/tables/time-series/demo/popest/2020s-national-detail.html), <https://www.census.gov/data/tables/time-series/demo/popest/2020s-national-detail.html>

Table 7: NEISS Estimates for Adult Bed Rail Injuries by Disposition

Disposition	Estimate	Sample Size
Treated and released, or Examined and released without treatment	70,100 (88%)	1,721
Treated and admitted for hospitalization, or Held for observation	8,900 (11%)	214
Left without being seen, or Left without treatment	** (<1%)	10
Death	** (<1%)	1
All Severities	79,500	1,946

Source: NEISS (2003-2021).

Estimates rounded to nearest 100; estimates that failed to meet NEISS publication criteria are presented as **. Rows may not add to total due to rounding.

Table 8 presents a breakdown of the injured patients by age and gender. Around 64 percent of the injuries occurred to females, and around 55 percent of the injuries occurred to patients 60 years or older.

Table 8: NEISS Estimates for Adult Bed Rail Injuries by Age & Gender

Age Group (Years)	Male	Female	Total
13–29	5,500	7,000	12,500 (16%)
30–59	8,500	15,000	23,500 (30%)
60–79	7,900	11,600	19,600 (25%)
80 or older	7,000	16,800	23,800 (30%)
Total	29,000 (36%)	50,500 (64%)	79,500 (100%)

Source: NEISS (2003-2021).

Estimates rounded to nearest 100 may not add to total due to rounding.

Table 9 presents a breakdown of the most frequent body parts injured in adult bed rail incidents. Note that many cases listed two body parts injured; the below table only provides a distribution of the primary body part injured.

Table 9: NEISS Estimates for Adult Bed Rail Injuries by Primary Body Part

Primary Body Part	Estimated Injuries
Head/Face	20,300 (26%)
Foot/Toe	11,200 (14%)
Lower Leg	9,600 (12%)
Hand/Finger	7,400 (9%)
Upper Trunk (excluding shoulders)	7,200 (9%)
Lower Trunk	5,600 (7%)
Lower Arm	3,100 (4%)
Knee	2,700 (3%)
Shoulder	2,200 (3%)
Ankle	2,200 (3%)
Other	8,000 (10%)
Total	79,500 (100%)

Source: NEISS (2003-2021).

Estimates rounded to nearest 100 may not add to total due to rounding.

Table 10 details the most common primary injury diagnoses. Note that some cases listed multiple diagnoses; the below table only provides a distribution of the primary injury diagnosis.

Table 10: NEISS Estimates for Adult Bed Rail Injuries by Diagnosis Type

Diagnosis Type	Estimated Injuries
Contusion or Abrasion	22,300 (28%)
Laceration	19,700 (25%)
Fracture	10,100 (13%)
Internal Organ Injury	7,300 (9%)
Strain or Sprain	4,000 (5%)
Hematoma	2,100 (3%)
Avulsion	1,300 (2%)
Other/Unspecified	12,600 (16%)
Total	79,500 (100%)

Source: NEISS (2003-2021).

Estimates rounded to nearest 100 may not add to total due to rounding.

The injury patterns and distributions of injuries by disposition, age/gender, body part, and diagnosis type were very similar to those presented in the previous memorandum.

Compliance with the ASTM Standard

To assess compliance of APBRs to the new voluntary standard, ASTM F3186 – 17, CPSC staff considered sampling and testing a market sample of APBR models (66 models in the market as of 2018, per Directorate for Economics). This was the first sample compliance testing to be completed with the current voluntary standard by CPSC staff, conducted from 2018 through 2019. Given that no prior testing data are available regarding the compliance proportion, a range of possible compliance percentages were considered for 95 percent confidence intervals, with two possible precision levels: 0.1 and 0.15. Considering the resource limitations, EPHA staff recommended using a sample size of 35 and precision 0.15 to perform the compliance testing. Given the lack of information, a simple random sample was chosen as the best option for a representative sample. Staff testing showed that there were zero fully compliant models and that all samples collected failed at least one mechanical and all label tests.

A second round of testing was conducted in 2021, which involved collecting a sample of 17 models (from 55 models available on the market as of 2021, per Directorate for Economics); this includes all eight models that had entered the market since the previous round of testing, and a random sample of nine models from the population identified previously in 2018 and 2019. The second round of testing also found zero models that were fully compliant, and all models failed at least one mechanical and all label tests as well. EPHA concluded there is no significant compliance with the new voluntary standard of APBRs that are known to be in the market today. There is no compliance amongst models that have entered the market since the last round of testing in 2018 and 2019; additionally, no changes have been made to substantially increase compliance of the previously identified and tested models that are still available on the market.

Tab B: Memorandum by The Directorate for Health Sciences, Division of Pharmacology and Physiology Assessment



Memorandum

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

THROUGH: Mary Kelleher, Associate Executive Director
 Directorate for Health Sciences

Stefanie Marques, Ph.D., Division Director
 Division of Pharmacology and Physiology
 Directorate for Health Sciences

FROM: Suad Wanna-Nakamura, Ph. D.,
 Division of Pharmacology and Physiology Assessment
 Directorate for Health Sciences

SUBJECT: Health Sciences Assessment for the Notice of Proposed
 Rulemaking for Adult Portable Bed Rails

DATE: September 14, 2022

Introduction

This memorandum provides Health Sciences' (HS) assessment of incident data on deaths and injuries associated with hazard patterns related to the use of adult portable bed rails. The incident data were provided by staff of the Directorate for Epidemiology Division of Hazard Analysis (EPAH) (Zhang 2022, Tab A) for the period between January 2003 to December 2021. The incidents were limited to non-medical devices where the user age is 13 years or older. Incidents where the user's age is unknown or unreported were included in the count.

Background and Product Description

On April 29, 2014, at CPSC's request, ASTM started a subcommittee of the F15 Committee on Consumer Products and began developing a voluntary standard for APBR products. In August 2017, ASTM published ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. This memorandum provides information on hazard patterns and related injuries.

ASTM F3186 – 17 describes "portable bed rails and related products" as products installed by consumers and "not designed as part of the bed by the bed manufacturer." These products are used to reduce the risk of falling from the bed, and to assist users in getting in/out of bed, as well as sitting and repositioning in the bed (Figure 1).

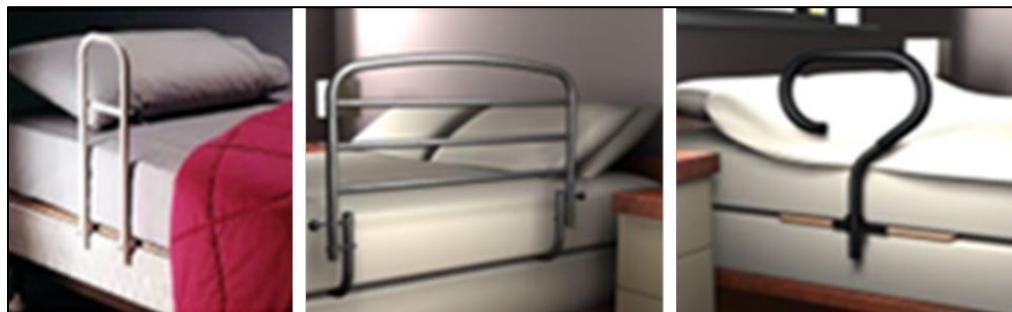


Figure 1: Examples of adult bed rails and grab bar images copied from various retailer and manufacturer websites.

Side rails and grab bars can be similar in design and overall shape. They are secured to the side of the bed primarily by two base rails, angled perpendicular to the main rail or bar, which slide between the mattress and box springs (Figure 2). Others have attachments that are product-specific.

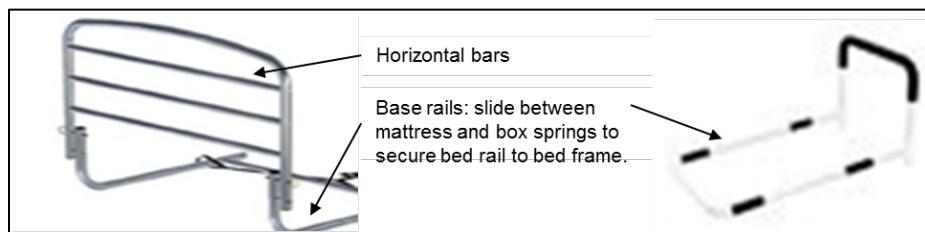


Figure 2: Bed rail components

Although similar in design, these products may have different functions. Some designs are meant to keep the occupant from rolling out of bed, and others are intended to assist an occupant in getting in and out of bed or repositioning on the bed surface. Some of these products can serve both functions. Because of the similarity in design and mechanism of attachment to the side of the bed, both types of products can have the same potential entrapment hazards.

Health Sciences staff has identified four sites related to APBRs where entrapments have occurred, although staff was unable to determine the exact entrapment location for 70 of the 284 reported fatal entrapment incidents. Based on the information provided in the incident data, the vast majority of incidents occurred in the space between the mattress and the inside surface of the APBR (Figure 3, zone #3); followed by under the horizontal bars of the side rail and the mattress, (Figure 3, zones #2 and #4); and in openings within the product (Figure 3, zone #1); and (D) in the space between the headboard/footboard and vertical end bar of the side rail (Figure 3, zone #6).

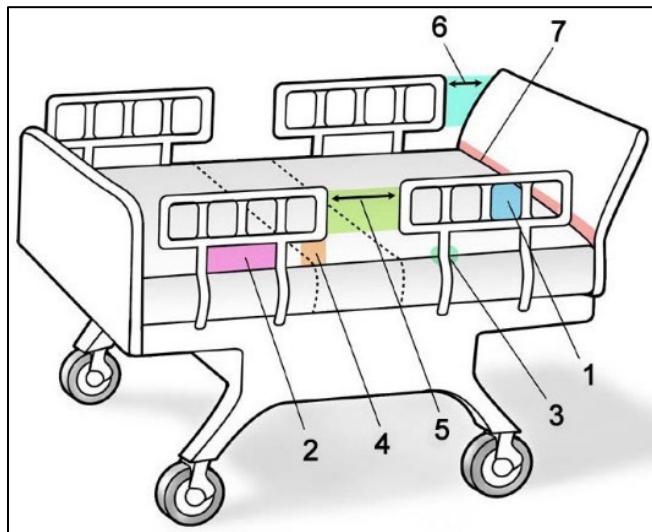


Figure 3: Zone identification^{1, 2}

Upper body entrapment between the mattress and side rail can lead to positional asphyxia by neck flexion or chest compression, or suffocation when the face is pressed against the mattress. Similar entrapments in hospital beds have been reported in the literature (US FDA, 2006 and Miles and Parker, 1998).

Incident Data

EPHA staff searched CPSC databases in the Consumer Product Safety Risk Management System (CPSRMS) for the period January 2003 to December 2021 (Zhang, 2022, Tab A) related to APBRs, using product code (4075). EPHA staff identified a total of 332 incident reports for this period. Of these, 310 were reports of fatalities, and 22 were incidents reporting noninjuries or “injury not reported.” CPSC staff conducted 74 In-Depth Investigations (IDIs). Eleven were terminated after attempts to reach the consumer failed. All deaths were unwitnessed and appear to have occurred while the victim was in bed.

Most of the incidents were identified from death certificates, medical examiner reports, or coroner reports. The remaining incidents were extracted from newspaper clippings, consumer reports, and manufacturer and retailer reports to CPSC. These documents contained limited information on incident scenarios for staff to assess actual causes. The age range of victims in the 305 fatal incidents where age was reported was 14 to 103 years, with most fatalities involving adults \geq 70 years old (Table 1). The vast majority of fatal incidents involved adults \geq 80 years 64% (199 of 305). Patient entrapments happened in private homes and inpatient care settings (e.g., hospice, assisted living, or long-term care facilities).

¹ Zone Descriptions: 1. Within the rail; 2. Under the rail, between the rail supports, or next to a single rail support; 3. Between the rail and the mattress; 4. Between the rail, at the ends of the rail; 5. Between split bed rails; 6. Between the end of the rail and the side edge of the head or foot board; 7. Between the head or foot board and the mattress end. Areas in Zones 5 and 7 are not relevant to APBRs (because they do not involve APBR components)

² Image Source: U.S. Food and Drug Safety Administration (FDA) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment>. (FDA, 2016- last accessed June 2022)

Table 1: Distribution of Reported Adult Bed Rail-Related Fatalities by Age Groups 2003 to 2021

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

Source: Zhang, A., 2022 Table 2., Tab A

HS and EPHA staff jointly reviewed and analyzed the incident data for medical condition and injury location categories. EPHA staff extracted all data under product code 4075³ for patients aged 13 years or older. Staff found that 286 of the fatal incidents and 23 nonfatal incidents involved body entrapment, including cases in which the victim was entrapped between the bed rail bars or between the APBR and an adjacent product; 23 fatal incidents involved falls from the bed and not entrapment (Zhang, 2022 Tab A). Ten incidents, including three fatal incidents, were categorized as “miscellaneous problems.” They included a death from hanging due to clothing becoming caught on the rail; hand, arm, or leg laceration; and one incident resulting in a pinched radial nerve, which is a serious injury. The most frequently reported injuries were to the neck and head.

Of the 310 fatal incidents, 187 (60%) reported that the victims had one or more preexisting chronic medical conditions or disorders (), which included Alzheimer’s disease, dementia, and other mental limitations; Parkinson’s disease; cerebral palsy; multiple sclerosis; Lesch-Nyhan syndrome⁴; amyotrophic lateral sclerosis; cancer; cardiovascular disease; and pulmonary disease. The list included victims with stroke, 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 often cannot respond to the danger and free themselves.

Table 2: Distribution of Reported Adult Portable Bed Rail-Related Incidents by Medical Conditions 2003 to 2021

Medical Conditions	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	10	0	10
Cancer	7	0	7
Cerebral palsy	6	0	6
Multiple sclerosis	5	0	5
Other	20	0	20
Unknown/Not reported	123	21	144

Source: Zhang, 2022 Table 5 Tab A

³ Product code 4075 encompasses all bed rail products.

⁴ A rare genetic disease characterized by neurological and behavioral abnormalities and occurs almost exclusively in males.

A review of the IDIs confirmed that product types, like those shown in Figure 1, were involved in one or more incidents. The victim was typically found with their torso between the product and the mattress frame, with their neck resting on the lower bar (Figure 4, A and B). Three other hazard patterns were also reported: (1) chin resting on the bar (Figure 4, C and D); (2) patient slumped backwards, partially suspended with the thorax lodged and compressed in the gap between the rail and mattress (Figure 4 E); and (3) slumped through the bar opening (Figure 4, F). The medical examiners in these cases listed the causes of death as “positional asphyxia,” with an additional list of “underlying factors” or “contributory causes.”



Figure 4: Images showing victims in areas and manner of entrapment in different types of adult bed rails; Source: IDIs. Victim and bedrail

HS 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. Sustained external pressure on the neck can lead to “asphyxia,” defined in medical literature as the failure of cells to thrive in the absence of oxygen. As previously detailed in HS staff memo (Wanna-Nakamura, 2021) neck compression, with or without airway blockage, can result in death, even when the body remains partially supported. 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.

Conclusion

HS staff evaluated the role that bedrails have played in entrapment deaths. HS staff found that in most cases, the cause of death was asphyxia due to entrapment, as determined by the medical examiner or coroner.

There are several factors to be considered in this evaluation. Most of the fatalities involving APBR entrapment were adults 80 years and older (191 of 295, or 65%).⁵ This is a potentially vulnerable population associated with an overall progressive decline in muscle strength, balance, and cognitive abilities. This population is also increasingly susceptible to a variety of ailments prevalent among the elderly. In addition to these age-related issues, more than half of the entrapment victims had other serious risk factors that were physical or neurological in nature. Conditions that limit mobility or reduce mental acuity can increase vulnerability and risk of entrapment and falls because they reduce the ability of victims to self-rescue when entrapped. There are reported instances where the APBR may have been installed improperly, which would have contributed to the life-threatening entrapment. Overall, the injury patterns, the medical condition of patients, and the entrapment areas within the product were similar to those previously reported. (Wanna-Nakamura, 2022).

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Tab C: Memorandum by The Directorate for Engineering Sciences, Division of Human Factors

Memorandum

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

THROUGH: Mark Kumagai, Associate Executive Director
 Directorate for Engineering Sciences

Celestine Kish, Acting Division Director
 Division of Human Factors,
 Directorate for Engineering Sciences

FROM: Zachary Foster, Industrial Engineer,
 Division of Human Factors,
 Directorate for Engineering Sciences

SUBJECT: Human Factors Engineering Analysis for the Notice of Proposed
 Rulemaking for Adult Portable Bed Rails

Background

CPSC staff worked with ASTM to develop a draft voluntary standard, and in August 2017, ASTM published the voluntary standard F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. The voluntary standard includes performance requirements, labeling and warning requirements, and instructional literature requirements intended to minimize entrapment and strangulation hazards associated with APBRs.

Starting in fiscal year 2018 (FY 2018), staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF) examined 35 samples to assess conformance with the labeling, warning, and instructional literature requirements of the standard and determined that none of the samples fully conformed to the standard's requirements.

Based on testing conducted in FY 2018, staff submitted an informational briefing package to the Commission in 2020, which evaluated whether ASTM F3186 – 17 is likely to result in the elimination or adequate reduction of the risk of injury and death identified in the petition and whether there is substantial compliance with the standard, as required by section 9(i) of the CPSA, 15 U.S.C. § 2058(i). Although staff concluded that the standard would adequately reduce the risk of injuries and death detailed in the petition, staff found no market compliance with the standard among the samples evaluated. To assess the likelihood of substantial compliance with the standard in the future, staff recommended that the Commission allow additional time for industry to adopt the standard and further determined that another round of market compliance testing would be necessary.

Staff performed a second round of evaluations in 2021, to determine if there was any change in market compliance to the standard. This testing was performed on 17 new APBR models available in the market, and again, staff concluded that none of the products met all the requirements of the standard.

In this memorandum, ESHF staff discusses the incident data relevant to APBRs and summarizes staff's findings from previous APBR briefing packages, which discussed labeling, warning and instructional literature requirements, as well as market compliance to ASTM F3186-17.

Incident Data Review

Staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA), has identified 332 incidents—310 fatalities and 22 nonfatal incidents and complaints—involving portable bed rails that occurred from January 2003 through December 2021 (Zhang, 2022; see Tab A). These victims ranged in age from 14 to 103 years old. Many of the incident reports are death certificates and medical examiner or coroner reports, and therefore, they have limited details on the circumstances of the incidents.

The most common hazard pattern among all reported incidents is rail entrapment, accounting for 284 of 310 fatal incidents. Rail entrapment incidents include cases 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.

ASTM F3186 – 17's entrapment testing assesses the potential for entrapment in four different zones in and around the APBR. These zones represent four of the seven entrapment zones identified by the U.S. Food and Drug Administration (FDA) in its 2006 document, *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment*,¹ as potential areas of entrapment in hospital bed systems. The guidance outlined in the document is based on recommendations from the Hospital Bed Safety Workgroup (HBSW), which was formed in 1999, to address reports of patient entrapment (FDA, 2006).²

Table 1 identifies³ and briefly describes the four entrapment zones tested in ASTM F3186 – 17 and includes illustrations from the 2006 FDA guidance document of sample entrapments within each of these zones.

¹ As of the date of this memorandum, this FDA document can be found online here: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment>. (FDA, 2016)

² 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 from 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 U.S. Consumer Product Safety Commission to improve patient safety associated with the use of hospital beds.

³ The zone names are from section 8.4 of ASTM F3186 – 17.

Table 1: Four Entrapment Zones of ASTM F3186 – 17

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

The other three entrapment zones identified by the FDA are not applicable to APBRs or do not lend themselves to entrapment testing:

- Zone 5 is the area between two side rails on the same side of the bed. Generally, only a single APBR is installed on any given side of a bed. Although CPSC staff is aware of one APBR that contains two separate rails that are installed on the same side of the bed, currently, staff is not aware of any incidents that have been identified as Zone 5 entrapments.
- Zone 6 is the area between the end of the rail and 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. This is addressed below in staff's discussion of the labeling and warning requirements.
- Zone 7 does not involve an APBR at all, and instead, it involves the space between the end of the mattress and the headboard or footboard. Thus, this zone is not applicable to APBRs.

Although the details surrounding many rail entrapment incidents are limited, the four zones of an installed APBR that are tested for entrapment appear to cover virtually all the known entrapment-related fatalities. ESHF staff's review of the available incident data found that about 200 of the 284 reported rail entrapment fatalities involved entrapment between the APBR and the mattress/bed. Of the 200 cases, staff determined that at least 29 appear to have been between the APBR and the mattress, or Zone 3,

and four cases were entrapments “under” the APBR and against the mattress, meaning Zone 2 or 4. The remaining 167 mattress-entrapment cases, most likely occurred within Zones 2, 3, or 4. Staff also concluded that at least eight of the 284 reported entrapment fatalities involved entrapment within the APBR itself, or Zone 1.

At least five cases appear to involve entrapment against the exterior of the APBR by another object, such as a commode or dresser. This location is outside the four zones tested by the standard. One case, possibly two, involved entrapment between the APBR and a headboard. This area is identified as Zone 6 in the 2006 FDA guidance document. Although this area is not tested for entrapment within the standard because it is dependent on where the consumer chooses to install the APBR on the bed, it does require warnings indicating a safe installation location relative to Zone 6. Staff was unable to identify the specific entrapment location in the remaining 68 cases. Table 2 summarizes these conclusions.

Table 2: 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

These results illustrate that nearly all cases of rail entrapment for which ESHF staff could determine the entrapment location (208 of 214 incidents) occurred in one of the four zones of entrapment tested in ASTM F3186 – 17. So, most rail entrapment incidents that occurred in an unknown location probably also involved one of these four zones. Staff’s finding that the preponderance of rail entrapments occurred in Zones 1 through 4 is consistent with the FDA’s finding that these four zones accounted for about 80 percent of entrapment events reported to the FDA that were associated with hospital bed systems. Moreover, this finding was the basis for the FDA recommending dimensional limits for these zones (FDA, 2006).

Some noteworthy details about the rail entrapment incidents:

- Three incidents involved the use of an APBR with an atypical bed. One incident involved a waterbed, one involved an air mattress, and one involved an adjustable bed.
- Some incidents are known to have involved APBRs that were not “secured” to the bed, and they only appeared to rely on the friction of the portion of the product that extends between the mattress and box spring (the “arms”) to hold the APBR in place. In one case, the product reportedly did not come with “safety straps” to secure the APBR, even though the product instructions showed them. In another case, the APBR was not secured to the bed with a “safety strap,” even though the product currently is sold with one. In another case, the person who installed the APBR reported difficulty in securing the retention strap due to its length. This person stated that the strap was “unclipped,” but they noted that the APBR was still secure.
- Two incidents report that the victims did not die during entrapment. Instead, the victims suffered injuries during their respective entrapments, developed complications from those injuries, and died later.

Previous ESHF staff memoranda regarding the APBRs have discussed adult aging issues that can contribute to entrapments, including age-related declines in muscular strength, muscular power, motor control and coordination, and balance (Smith, 2014).⁴ Consumers 80 years and older, who represent the victims in most APBR-related fatalities, are especially vulnerable to such declines. About three-fifths of all APBR-related fatalities involved a victim who had at least one underlying medical condition, and it is reasonable to conclude that some of these conditions contributed to the incidents. Also, consumers commonly purchase and use APBRs because they require help when getting in or out of bed. For example, some cases involved a consumer who was bedridden or used a wheelchair. Therefore, many APBR users would likely be less capable of escaping an entrapment scenario than the general population.

EPHA staff identified falls as the second most common hazard pattern associated with APBRs, accounting for 25 incidents, 23 of which resulted in fatality. One fall involved the vertical rail of the APBR that had not been raised to an upright position. Another incident apparently involved a consumer who fell despite, rather than because of, the presence of the APBR. Five incidents reportedly involved the victim climbing over the APBR, with one report specifically stating that the victim “apparently” climbed over the product. Another of these cases reported the victim climbed over the APBR because he was unable to lower the product. Fifteen incidents involved the victim falling against or otherwise striking the APBR. The product might have played more of an incidental role in these cases:

- Seven of these 15 cases occurred while the victim was in bed, getting out of bed, or trying to sit on the bed. However, the incident reports do not include any details suggesting that the APBR contributed to the fall. One separate incident occurred when the victim was being removed from her bed by long-term care facility staff.
- Three cases involved the victim falling from a standing position and striking the APBR.
- Six cases did not include any details about the circumstances of the incident.

Labeling, Warning, and Instructional Literature Requirements

On August 30, 2017, ASTM published F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*.⁵ The standard, intended to minimize entrapment and strangulation hazards, includes specific requirements labeling and warning for APBRs and their packaging, as well as for instructional literature.

Labeling Requirements

Section 9 of ASTM F3186 – 17 specifies requirements for APBR labeling and warnings. Section 9.1 states that the product and its retail packaging must be marked or labeled with:

- the type and size of beds and mattresses, including the mattress thickness range, for which the product is intended (*i.e.*, compatible beds and mattresses);

⁴ See Smith (2005) for a detailed discussion of these and other age-related differences in the adult consumer population.

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

- the appropriate distance between an installed APBR and the headboard or footboard of the bed; and
- the name, place of business (city, state, and mailing address, including zip code), and telephone number of the manufacturer, importer, distributor, or seller. The listed entity must be able to answer technical questions about installation and use, and they also must be able to receive complaints.

This section also specifies that all on-product labels must be permanent.

Products (but not packaging) are required to be labeled with a statement indicating that they are under the jurisdiction of either the FDA or the CPSC and must display contact information for the respective agency.

Section 9.1.1.3 requires labeling stating that the APBR shall be installed greater than 12 ½ inches or less than 2.4 inches from a headboard or footboard.

Warning Requirements

Section 9.2 of ASTM F3186 – 17 specifies requirements for warnings that must appear on the APBR and its retail packaging, instructions, and Internet or print advertising. This section of the standard identifies three sets of warning statements, shown below in Figures 1, 2, and 3:

The voluntary standard requires that the retail packaging, product instructions, and Internet or print advertising for the product include the warning statements below:

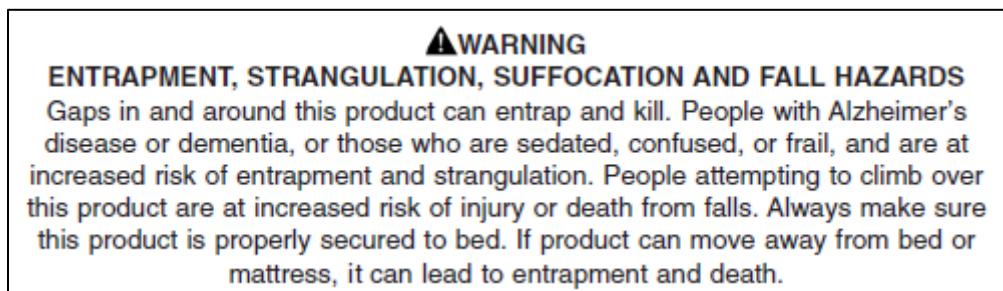


Figure 1: Warning Statement for Packaging, Instructions, and Internet/Print Advertising.

Product Warning Statements

The voluntary standard also requires the following warning statements on the product, in the product instructions, and in Internet or print advertising for the product:



Figure 2: On-Product Warning

“Conspicuous Component” Warning Statements

Lastly, the voluntary standard requires that at least one “conspicuous component” of the product be labeled with the following warning statement:

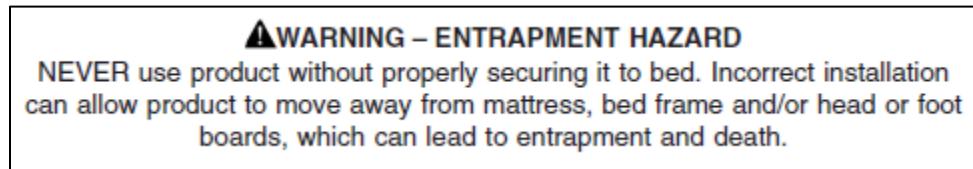


Figure 3: “Conspicuous Component” Entrapment Warning

The children’s portable bed rail standard (16 CFR § 1224) includes a requirement for a similar warning to appear on at least one “installation component,” which is defined as a component of the bed rail that is designed specifically to attach the bed rail to the bed and that typically is located under the mattress when in the manufacturer’s recommended use position. The intent of the requirement was to improve the likelihood that consumers will use that component to install the product properly. During the development of ASTM F3186, ESHF 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 standard does not define this phrase, but it defines “conspicuous” in Section 3.1.3 as “visible, when the product is in the manufacturer’s recommended use position, to a person standing near the unit at any one position around the unit but not necessarily visible from all positions.” ESHF staff continues to recommend that this warning should appear on an installation component for the following reasons:

- The warning, as used in 16 CFR § 1224, is intended to draw attention to the installation component and to encourage its use.⁶

⁶ Staff is aware of two rail entrapment fatalities involving APBRs that were not secured to the bed with a “safety strap,” even though the products currently are sold with one. However, for one of these fatalities, it is unknown whether the product was sold with a strap at the time of purchase.

- 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. In other words, requiring the warning to be on a “conspicuous component” most likely would not permit the warning to be placed on an installation component. Yet, drawing attention to the installation component was the original purpose of the warning.
- The warning shown in Figure 2 above, which also discusses entrapment hazards and keeping the product tight against the mattress, is required to be placed on a “conspicuous” portion of the product.

Therefore, staff proposes that “conspicuous component” be changed to “installation component” and that a definition for “installation component” be provided in the proposed language for a mandatory standard (see Howie, 2022; see Tab F).

Other Warning Requirements

In addition to specifying the warning content, Section 9.2 includes other requirements related to warnings. For example, ASTM F3186 – 17 specifies the placement of warnings on the product, by requiring warnings to be “conspicuous,” which the voluntary standard defines in Section 3.1.3 (see above). Many ASTM standards include a similar “conspicuous” requirement for warnings and define this term to allow the consumer to assess conformance to that requirement for themselves. The definition of APBR requires the warnings to be visible to the consumer, even after the product has been installed (*i.e.*, in the “manufacturer’s recommended use position”), which increases the likelihood that warnings are visible when needed.

ASTM F3186 – 17 also includes the following format requirements for warnings:

- The warnings must be in highly contrasting colors and in non-condensed sans serif type.
- Each group of warning statements must be preceded by a safety alert symbol (▲)⁷ and the specified signal word (for example, “WARNING”).
- The safety alert symbol and signal word must be in letters at least 0.2 inches (5 mm) high, and the rest of the warning text must be characters whose upper case is at least 0.12 inches (3 mm) high.

Lastly, ASTM F3186 – 17 requires that the warnings be permanent, easy to understand, in English, at least, and that any other labels or written instructions provided in addition to those required by the standard cannot contradict or confuse the meaning of the required warnings, or otherwise be misleading.

ESHF staff assesses that these warning requirements are adequate and should be adopted into the final rule.

Instructional Literature Requirements

Section 11 of ASTM F3186 – 17 specifies requirements for instructional literature or “instructions” that must accompany APBRs. These requirements include the following:

⁷ The version of the safety alert symbol shown here is based on the default symbol used in the ANSI Z535 series of standards. For consistency, ESHF staff uses this version throughout the memorandum for all instances of the safety alert symbol.

- The instructions must be easy to read and understand.
- The instructional literature must include assembly, installation, maintenance, cleaning, operation, and adjustment instructions and warnings, where applicable.
- The instructions must include drawings or diagrams to provide a better understanding of set up and operation for use and must include drawings that depict all the entrapment zones.
- The instructions must include all warning statements specified in Section 9.2 of the standard (discussed earlier in this memorandum).
- The instructions must include the following additional warning statements⁸:
 - “Stop using immediately if damaged or broken, or if parts are missing.”
 - “Stop using immediately if product shifts out of its original position until it is readjusted into the correct position.”
 - “In addition to contacting the manufacturer directly, consumers should report problems to the CPSC at its [sic] website SaferProducts.gov or call 1-800-638-2772, or to the FDA at 1-800-332-1088.”
 - “For further information, see: cpsc.gov/en/Safety-Education/Neighborhood-Safety-Network/Posters/Adult-Bed-Rails/ and www.fda.gov/bedsafety.”
- Products that use straps to meet the standard’s retention system requirements must include “WARNING: If the strap provided is not properly secured the product may move into an unsafe position which increases the danger of entrapment. See instructions for proper use of the straps.”
- All warnings in the instructions must meet the same design or formatting requirement as the product warnings.

ESHF staff notes with “[sic]” in the bullet list above, the statement in Section 11.1.1.3 of ASTM F3186 – 17 includes a typographic error, with “is” used in place of “its.” Staff proposes correcting this error in the final rule (see Tab F). Additionally, ESHF staff notes that the CPSC link above is no longer active. ESHF staff recommends updating the link to: cpsc.gov/safety-education/safety-guides/furniture-furnishings-and-decorations/adult-bed-rails.

Overall, ESHF staff note the “safety hierarchy” is a recognition that the safest approach to eliminating risk is to perform a redesign which removes the hazard. If redesigning is not feasible, then the next best approach is to employ a guard or barrier to separate the user from the hazard. And if a guard is not feasible, then the next step is to use a warning. ESHF staff note that although warnings and instructions have limited effectiveness, staff assesses that the labeling, warning, and instructional literature requirements of ASTM F3186-17 provide important warnings and information about the risk of injuries and deaths associated with APBRs and recommends that they be adopted in the final rule, with the exception that “conspicuous component” be changed to “installation component” in section 9.2.7, as noted above.

⁸ Some required statements refer consumers to both CPSC and FDA because ASTM F3186 – 17 covers APBRs that meet the definition of a “medical device,” and therefore, are under the jurisdiction of FDA, and covers other APBRs that are under the jurisdiction of CPSC.

Industry Compliance to ASTM F3186-17

To determine the level of market compliance to the standard, LSM and ESHF staff conducted two rounds of testing on APBR models available on the market. The first round of testing, conducted in 2018, and 2019, determined the baseline level of compliance in the market after the standard was published in 2017. The second round of testing was conducted in 2021, to determine if APBR manufacturers had adopted the standard and made changes to their products to comply to the ASTM F3186-17 standard. Results from both rounds were used to determine if substantial compliance would be likely.

2018 APBR Market Compliance Testing

In 2018, to assess industry compliance with ASTM F3186 – 17, CPSC staff collected 35 sample APBRs that staff of CPSC's Directorate for Economic Analysis (EC) and EPHA determined to be representative of the market. ESHF staff examined the sample products to assess sample conformance to the labeling (Section 9.1), warning (Section 9.2), and instructional literature (Section 11) requirements. ESHF staff found that none of the 35 sample APBRs fully complied with any of these sections. A comprehensive discussion of ESHF staff findings can be found in a prior briefing package.⁹

2021 APBR Market Compliance Testing

In 2021, CPSC staff collected an additional 17 sample APBRs for evaluation and testing. Eight of these samples comprised of all the new models that had entered the market after the first round of testing in 2018. The remaining nine samples had been identified previously by EC staff in 2018, and still available in 2021. ESHF staff examined the sample products to assess their conformance with the labeling (Section 9.1), warning (Section 9.2), and instructional literature (Section 11) requirements, applying the same methodology used on the 35 samples detailed in the 2020 briefing package. ESHF staff found that none of the 17 sample APBRs fully complied with any of these sections. A comprehensive discussion of ESHF staff's findings can be found in a prior briefing package.¹⁰

For both rounds of testing, the results indicate that APBRs currently on the market do not comply to the labeling, warning, and instructional literature requirements of the standard.

Conclusion

Most incidents associated with APBRs are rail entrapments, in which the victim becomes entrapped in or against the APBR, and these incidents most commonly involve entrapment between the APBR and the mattress, or bed. Consumers 80 years and older, who make up most fatalities, are especially vulnerable to age-related declines in muscular strength, muscular power, motor control and coordination, and balance. Adult aging issues such as these, as well as preexisting medical conditions, most likely

⁹ See Smith, T. P. and Talcott, K. (2020). Tab D. *Human Factors Assessment of ASTM F3186 – 17, Standard Specification for Adult Portable Bed Rails and Related Products, and Likely Industry Compliance to Certain Requirements of the Voluntary Standard*. [CPSC staff memorandum to Vineed K. Dayal, Project Manager, Adult Portable Bed Rails, U.S. Consumer Product Safety Commission, Rockville, MD.](#)

¹⁰ See Foster, Z. (2022). Tab D. *Human Factors Assessment of ASTM F3186 – 17, Standard Specification for Adult Portable Bed Rails and Related Products, and Likely Industry Compliance to Certain Requirements of the Voluntary Standard*. [CPSC staff memorandum to Vineed K. Dayal, Project Manager, Adult Portable Bed Rails, U.S. Consumer Product Safety Commission, Rockville, MD.](#)

contribute to entrapments, and these consumers are less capable of escaping an entrapment scenario than the general population.

The primary performance requirement in ASTM F3186 – 17 intended to address APBR hazards is entrapment testing, which assesses the entrapment potential in four zones in and around an installed APBR. These zones account for virtually all known entrapment fatalities, and testing is performed using a probe that is based on key anthropometric dimensions of at-risk consumers. Thus, ESHF staff concludes that a properly installed APBR that passes this entrapment requirement would effectively address the entrapment hazard. ASTM F3186 – 17 also includes performance requirements intended to address misassembly and misinstallation, as well as requirements for labeling, warnings, and instructional literature.

Although hazard control measures 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, particularly if the victims are older adults, ESHF staff concludes that labeling, warnings, and instructions offer some benefit as a supplemental safety measure for risks that cannot be eliminated through design.

Based on its examination of APBR samples, determined to be representative of the market, ESHF staff, at this time, concludes that industry compliance with the labeling, warning, and instructional literature requirements of ASTM F3186 – 17 is very low. No samples evaluated by ESHF staff fully conform to the labeling requirements, warning requirements, or instructional literature requirements. ESHF staff assesses that, by adopting ASTM F3186-17 as a mandatory standard, APBR manufacturers will communicate more effectively hazards associated with APBRs and address proper assembly and installation of APBRs.

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Tab G, 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.

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Tab D: Memorandum by The Directorate for Laboratory Sciences, Division of Mechanical Engineering



Memorandum

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

DATE: September 14, 2022

THROUGH: Andrew G. Stadnik, Associate Executive Director,
 Directorate for Laboratory Sciences

Michael Nelson, Division Director,
 Division of Mechanical Engineering,
 Directorate for Laboratory Sciences

FROM: Greg Ota, Mechanical Engineer,
 Division of Mechanical Engineering,
 Directorate for Laboratory Sciences

SUBJECT: Mechanical Engineering Analysis for the Notice of Proposed
 Rulemaking for Adult Portable Bed Rails

Introduction

CPSC staff worked with ASTM to develop a draft voluntary standard, and in August 2017, ASTM published the voluntary standard F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. The voluntary standard includes performance requirements, labeling and warning requirements, and instructional literature requirements intended to minimize entrapment and strangulation hazards associated with APBRs.

Starting in fiscal year 2018 (FY 2018), CPSC's Directorate for Laboratory Sciences, Division of Mechanical Engineering (LSM) staff conducted compliance testing on 35 randomly selected APBR models available in the market and determined that none of them met the safety requirements of the standard.

Based on this testing, as required by section 9(i) of the CPSA, 15 U.S.C. § 2058(i), staff evaluated whether ASTM F3186 – 17 is likely to result in the elimination or adequate reduction of the risk of injury identified in the petition, and whether there is substantial compliance with the standard. Staff reported its conclusions to the Commission in a briefing package dated July 15, 2020. Although staff concluded that the standard would adequately reduce risk of injuries detailed in the petition, staff found no compliance to the standard within the samples tested. Staff determined that another round of compliance testing would be necessary to assess the likelihood of substantial future compliance to the standard. Accordingly, staff recommended that the Commission allow additional time for industry to adopt the standard.

In 2021, LSM staff performed a second round of testing to determine if there was any improvement in compliance to the standard. This testing was performed on 17 new APBR models available in the market, and once again, staff determined that none of the products met all the requirements of the standard. In a March 9, 2022 staff briefing package, LSM staff presented an analysis of APBR models and their compliance to ASTM F3186 – 17. That memorandum summarized the results of the mechanical testing from these market compliance studies.

This memorandum presents a review of staff's testing and findings from previous APBR briefing packages, which discussed market compliance, common failures modes, and proposed changes made to ASTM. To fully understand CPSC staff's analysis of ASTM F3186 – 17, CPSC's Human Factors staff's (Tab C) analysis must be considered in conjunction with this memorandum. In addition to inadequate mechanical design components, several of the issues related to product failures are associated with insufficient warnings and a lack of adequate instructions, which contribute to the potential user's misperception of safe product use.

Studies of Market Compliance to ASTM F3186-17

To determine the level of APBR compliance with the ASTM F3186 – 17 standard, staff conducted two rounds of testing on APBR models available on the market. The first round of testing, conducted in 2018 and 2019, determined the baseline level of compliance in the market after the standard published in 2017. To determine if firms had adopted the standard and made changes to APBRs to comply with ASTM F3186 – 17, staff conducted a second round of testing in 2021. Results from both rounds were used to determine if substantial compliance would be likely. For each round of testing, CPSC's Directorate for Economic Analysis staff conducted a market analysis to identify all unique APBR models available on the market. Staff identified 66 models in 2018, and 58 models in 2021.¹ In 2018, staff of the Directorate for Epidemiology, Division of Hazard Analysis determined a randomly selected sample of 35 unique APBR models would be adequate to statistically represent the market at a 95 percent confidence interval with 0.15 precision.² In 2021, staff determined that all eight new models that had entered the market since 2018, would be tested, in addition to a random sampling of nine remaining models that had been previously identified in 2018, and were still available in 2021. Staff collected the sample set and tested all products to determine if they complied with ASTM F3186 – 17. This memo summarizes the results of the mechanical tests and will include testing from Section 9.1.2, Label Permanency. This memo will not cover other requirements addressing warnings, labels, or other informational literature, which are covered in Tab C.

2018 Market Compliance Study

In 2018, LSM staff tested a sample set of APBR models available in the market to evaluate compliance with the new standard. The sample set consisted of 35 APBR models, which, according to CPSC epidemiological and economic analyses, were representative of the entire APBR market at the time. The market samples included products from approximately 87 percent of all APBR manufacturer or importer firms known to staff, including the largest APBR manufacturers.

¹ 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>

² 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.

Staff found that none of the samples tested met all the requirements in F3186-17, and most samples failed multiple sections. Detailed testing results are provided in Appendix A.³ A comprehensive discussion of LSM staff findings can be found in a prior briefing package.⁴

2021 Market Compliance Study

In 2021, staff conducted an additional round of product testing to see if more time to adapt to the standard would lead manufacturers to comply. Seventeen APBR products were selected; eight of these models covered all the identified APBRs introduced to the market since 2018. The other nine out of 17 were new samples of models previously identified and tested in the 2018 analysis. To gauge compliance to the standard's mechanical performance requirements, LSM staff tested the sample products. LSM staff found that all 17 samples failed at least one mechanical requirement. Detailed testing results are provided in Appendix B.⁵ A comprehensive discussion of LSM staff findings can be found in a prior briefing package.⁶

For both rounds of testing, the results indicate that APBRs currently on the market do not comply to the mechanical performance requirements of the standard. These results also indicate that there has been very little change in the overall level of market compliance with the ASTM F3186 – 17 voluntary standard.

Common Product Compliance Failure Modes to ASTM F3186 – 17 Test Requirements

On August 30, 2017, ASTM International published ASTM F3186 – 17. The scope of the standard states that it is intended to minimize entrapment and strangulation hazards, and it includes general and specific performance requirements for APBRs.⁷ During both rounds of compliance testing, staff determined common modes of failure for the products, which indicate that the products tested did not meet the requirements of the standard. These failure modes are broken down by section below:

Section 6.1 - Retention Systems

Section 6.1 of the standard states that each product must meet three requirements: (1) it must have a method of maintaining the product's position; (2) the retention system must be permanently attached to the product; and (3) the retention system shall not slip or permanently deform during testing.

Staff found the primary retention system failure mode was components not permanently attached to the product, as shown in Figure 1 below. In other cases, 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.

³ Due to the nature of the test, 9.1.2 was considered a mechanical test. There were no products that met the remaining requirements of Section 9.1, Section 9.2 and Section 11.

⁴ Tab E, Dayal, V. Memorandum by The Directorate for Laboratory Sciences, Division of Mechanical Engineering, *Engineering Analysis of Petition CP 13-1, Requests for Ban or Standard on Adult Portable Bed Rails*, 2020.

⁵ 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.

⁶ Tab E, Howie, A. Memorandum by The Directorate for Laboratory Sciences, Division of Mechanical Engineering, *Engineering Analysis of Petition CP 13-1, Requests for Ban or Standard on Adult Portable Bed Rails*, 2022.

⁷ ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*, ASTM International, West Conshohocken, PA, 2017, www.astm.org.



Figure 1: Example of a retention system that was not permanently attached to the product.

Section 6.2 - Structural Integrity

Section 6.2 has two main performance requirements: (1) during the static structural height test, the product shall extend at least 4 inches above the top surface of the thickest mattress recommended by the product manufacturer; and (2) the product shall not change dimensions or create a hazardous condition during or after cyclic testing.

Most APBR manufacturers did not specify a recommended mattress height or provide instructions on how to adjust product features for a specific mattress. When this was the case, LSM staff selected any mattress readily available to the public that would create the most onerous test conditions allowed by the product and its instructions to meet the requirements. Staff determined that this was a reasonable approach to evaluating compliance to the standard, because no instructions were provided for adjusting the product features, and no mattress height was recommended by the manufacturer. The static height requirement, described in Section 6.2.1 of the standard, requires the product to extend a minimum of 4 inches above the top surface of the mattress. Adjusting the product to its lowest possible setting, and/or selecting the thickest recommended mattress, resulted in many products not meeting this requirement, as shown in Figure 2.⁸

⁸ Unless otherwise noted, the pictures used in this section are of a modular APBR design fabricated by LSM staff for demonstrational purposes only.



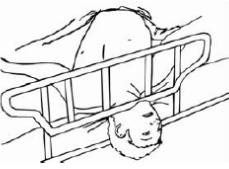
Figure 2: Demonstration of an APBR product failing the static height requirement in section 6.2.1.

The fasteners loosened or detached during cyclic testing in many of the products tested, which caused the product to change dimensions. This constitutes a failure under Section 6.2.2.

Section 6.3 - Entrapment

Section 6.3 requires that APBR products do not have one or more of the entrapment zones, as shown in Table 3 below. The zones are identified as follows: (1) Zone 1 - Within the rail; (2) Zone 2 - Under the rail between the rail supports, or under the rail next to a single rail support; (3) Zone 3 - Between the rail and the mattress; and (4) Zone 4 - Under the rail at the ends of the rail.

Table 1: Entrapment Zones

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

Zone 1 Testing

Many samples did not have adequate internal structure to prevent the head probe from passing through the Zone 1 opening, and these samples failed the Zone 1 entrapment requirements, as shown in Figure 3.

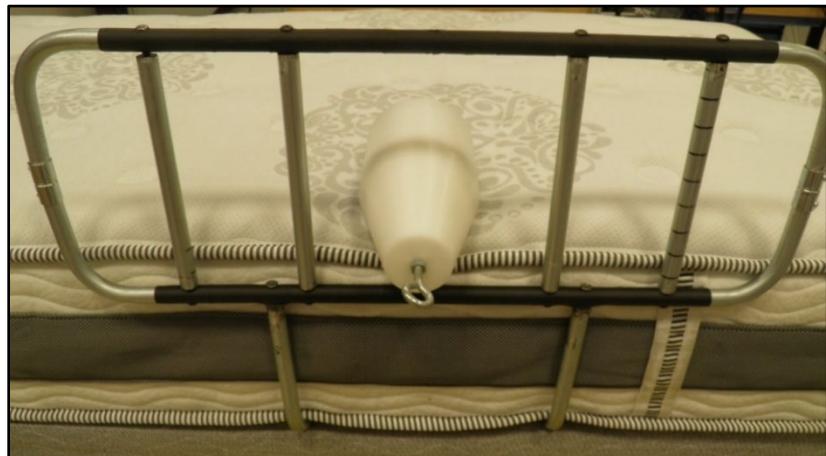


Figure 3: Demonstration of a product without sufficient Zone 1 internal structure.

Zone 2 Testing

APBR models failed Zone 2 requirements due to two issues. First, many models were designed without an internal structure to prevent the probe from entering the opening between the rail and the mattress, as shown in Figure 4.



Figure 4: Demonstration of a product without sufficient internal structure to cover the Zone 2 opening.

Second, many manufacturers did not specify what mattress thickness to use with the product, nor did they instruct consumers in how to install or adjust the product to fit different size mattresses properly. Figure 5 shows an example of a product with installation instructions that allowed for a significant lateral gap between the mattress and the product.



Figure 5: Demonstration of a product with a considerable gap between the mattress and the product (Zones 2 & 3).

Zone 3 Testing

The causes of the Zone 3 entrapment failures were similar to those of Zone 2: most failures occurred due to a lack of adequate structure and a lack of instructions for mattress compatibility. In some cases, the gaps between the product's internal crossbeams were significant and allowed the probe to move laterally outward, partially into the gap between the crossbeams, which reduced the amount of support the probe would receive from the mattress, as shown in Figure 6. When the surface area supporting the probe decreases, the probe deflects more into the mattress, resulting in a failure related to the maximum allowable vertical deflection. This deflection poses an entrapment hazard that may lead to asphyxia between the mattress and the APBR. One product that was tested used brackets that created a significant lateral offset between the bed frame, product, and the mattress. The gap between the product and the mattress allowed the probe to shift outward laterally, which reduced performance, as seen in Figure 7. The user manual also contributed to the lack of compliance to the standard. Some user manuals do not state explicitly that the APBR should be installed against the mattress, and some of these manuals include recommendations suggesting that this lateral gap can be as large as 2 inches. In addition, some user manuals that state that the APBR should be installed against the mattress, also suggest that the distance between the product and the mattress could be as large as 4.75 inches. The largest diameter of the test probe is 4.7 inches. The significant gap between the product and the mattress allowed the probe to fall completely through the opening or translate laterally outward, which reduced the amount of mattress supporting the probe. Both caused the products to not meet the performance requirements for Zone 3. This issue is discussed in more detail in the previous Human Factors memorandum, as well as LSM staff's memorandum in the 2020 Briefing Package.

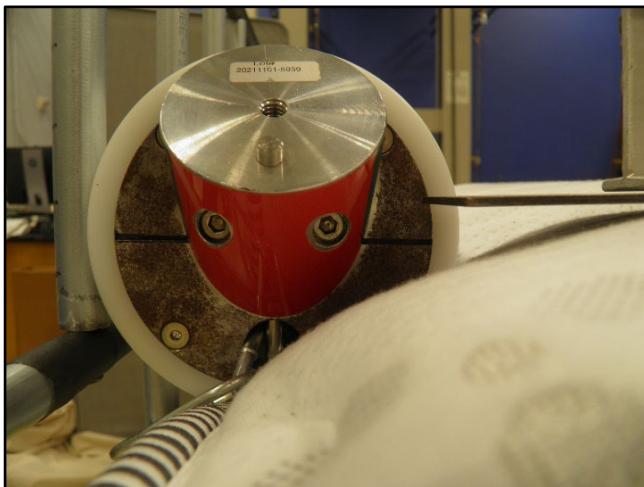


Figure 6: Demonstration of large gap between cross beams permitting the probe to sink below the surface of the mattress.

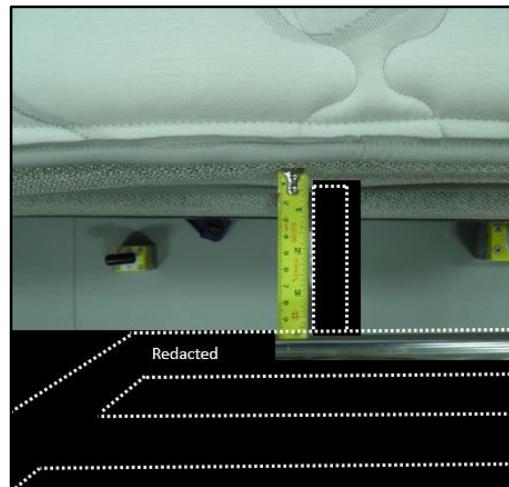


Figure 7: Example of large lateral gap between mattress and product allowed by the user manual.⁹

Zone 4 Testing

The Zone 4 entrapment failures were caused by overhanging structures at the ends of the rail. The overhanging structures were generally a result of the rail being positioned too high, relative to the mattress. Some products' geometry created large openings at the sides of the product, as seen in Figure 8. The test method for Zone 4 entrapment specifies that the product must be adjusted to the manufacturer's recommended height, or heights above the mattress, for products that allow consumer adjustment (see Section 8.4.6.3). In most cases, the manufacturer did not specify how to adjust or install the product for a given bed and mattress environment. As discussed in the previous 2022 Human Factors memorandum, many instructions for products with consumer-adjustable heights simply tell consumers to adjust the product to their preferred or desired height; or, the instructions simply describe how to adjust the height, without saying why consumers should do so. In the absence of clear instructions from the manufacturer, CPSC's technical staff chose to use any representative mattress available to the public, with the product adjusted to the most onerous position, as seen in Figure 9.

⁹ Figure 7, which depicts a test sample, has been redacted to preserve sensitive model information. Dotted white outlines are used to indicate the product's relative geometry and structure to the failure mode.



Figure 8: Demonstration of a structure that created a large opening at the ends of the rail.



Figure 9: Demonstration of overhanging structure that is too high relative to the mattress.

Section 6.5 - Misassembled Products

Section 6.5 requires that APBR products that require consumer assembly meet the requirements of Sections 6.1-6.4 if the APBR appears to be functional in any misassembled condition. For a more detailed description and interpretation of the requirements in this section, see the previous Human Factors Memorandum.

Most products that failed this section failed because the APBR products still appeared to be functional without the removable retention strap installed. Other products failed because they had user-installed structural beams, and when the beam was not installed it created an entrapment hazard.

Section 9.1.2 - Label Permanency

Section 9.1.2 establishes requirements for any warning labels present on the product, stating that the labels must be permanent, irremovable without the use of solvents or tools. The label is also considered permanent if removing the label results in damaging the surface on which it is affixed.

In many APBR samples tested, CPSC staff was able to remove the label without the use of any tools or solvents and without damaging the substrate, causing these units to fail to meet the requirements of Section 9.1.2, *Label Permanency*. An example of this can be seen in Figure 10 below.

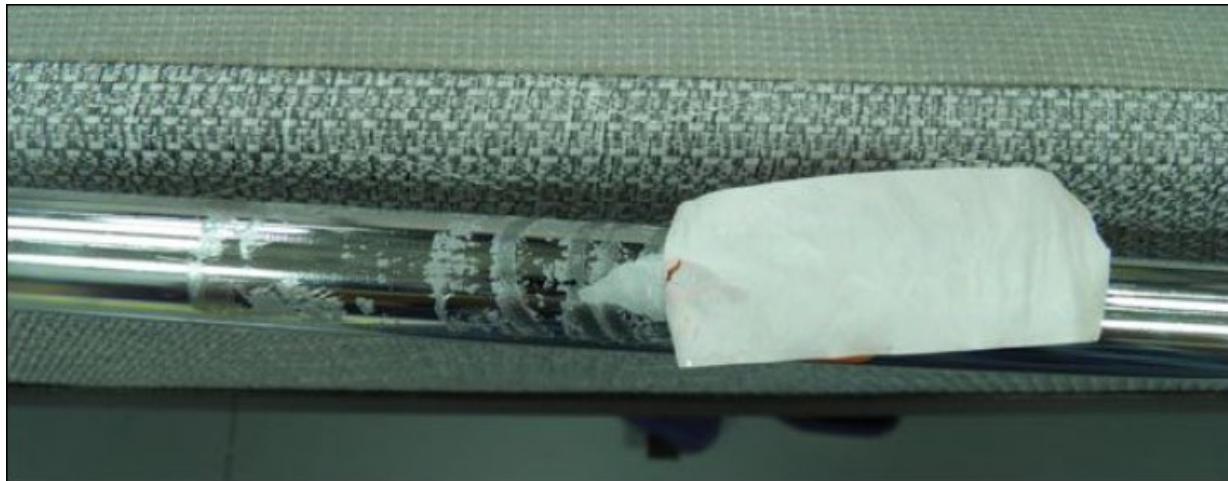


Figure 10: Example of a label being removed without damaging the substrate.

Conclusion

Staff reviewed ASTM F3186 – 17 and concluded that, with modifications and substantial market compliance, the standard would adequately address identified hazards related to adult portable bed rails.

Staff conducted two rounds of APBR market compliance testing to ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*, and concluded that there is no substantial market compliance to the standard.

In 2018, staff evaluated 35 unique APBR models, randomly selected to represent the market at large, and found that none of the products that were tested complied with all requirements of the standard. In 2021, Staff conducted a second round of testing to determine if there was any change in compliance in the current APBR market. Staff tested 17 randomly selected products, including all eight new and unique APBR models that had entered the market since the 2018 analysis. Staff determined that none of them fully complied with the standard. In both tests, all products tested failed at least one requirement in the voluntary standard, with some failing as many as five different subsections of the standard.

Staff has also been active at all ASTM F15.70 subcommittee meetings for Adult Safety Products, to share the results of the market compliance testing and to urge industry to make changes to their respective APBRs to satisfy the safety requirements of the voluntary standard. Despite this effort, as well as a letter from the Office of Compliance, staff has repeatedly found no APBRs that meet all the requirements of the voluntary standard.¹⁰

¹⁰ 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>.

Tab E: Memorandum by The Office of Compliance and Field Operations, Division of Enforcement and Litigation



Memorandum

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

THROUGH: Robert S. 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

DATE: September 14, 2022

This memorandum describes enforcement activities involving adult portable bed rails (APBRs) 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, their bed rails 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 provided a general acknowledgment that it had received the letter.

Section 15 Compliance Actions

Beginning in September 2020, Compliance contacted six bed rail manufacturers to initiate section 15 investigations. To identify firms to prioritize for these investigations, we reviewed incident data to 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).

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>.

As a result of these investigations, the CPSC has issued five public notices, described below. Two notices warned the public about products manufactured by firms that are no longer in business or that have not agreed to conduct recalls, and three other notices announced voluntary recalls.

In April 2021, CPSC warned consumers to stop using three models of APBRs manufactured by Bed Handles, Inc., 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 products failed to comply with the performance requirements of ASTM F3186 – 17.

Similar versions of the Bed Handles, Inc., 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 has 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 can only be removed 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, Inc., distributed approximately 193,000 products, including those previously recalled. CPSC is aware of four entrapment deaths involving bed rails distributed by Bed Handles, Inc.

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' 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 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 model.

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>.

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>.

Essential recalled four models of bed rails due to their 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; it 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 warned consumers to stop use and dispose of 10 models of APBRs manufactured and sold from 1992 to 2021, by Mobility Transfer Systems, Inc. (MTS), and in 2021 and 2022, by Metal Tubing USA, Inc. (MTU).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.

Compliance is continuing to review other APBRs for potential future enforcement action.

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, [CPSC Urges Consumers to Immediately Stop Use of Mobility Transfer Systems Adult Portable Bed Rails Due to Entrapment and Asphyxia Hazard; Three Deaths Reported | CPSC.gov](https://www.cpsc.gov/Newsroom/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).

Tab F: Proposed Changes to ASTM F3186-17



Memorandum

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

THROUGH: CPSC Adult Portable Bed Rail Project Team

DATE: September 14, 2022

FROM: Adam Howie, Mechanical Engineer,
 Division of Mechanical Engineering,
 Directorate for Laboratory Sciences

SUBJECT: Proposed Changes to ASTM F3186-17, Standard
 Consumer Safety Specification for Adult Portable Bed Rails
 and Related Products for NPR

Introduction

Staff proposes several modifications to ASTM F3186 – 17 to clarify certain sections, and improve safety, including:

- Providing additional definitions for “product assembly and installation” to ensure their consistent and differentiated use throughout the document.
- Including requirements for manufacturers to inform the consumer of the range of mattress thicknesses to ensure safe use of the product and provide testers with guidance for selecting the mattress thickness during the test setup.
- Addressing inconsistencies with stated dimensions to ensure consistent dimensional tolerances.
- Updating the requirements for Zone 3 testing to be consistent.
- Providing additional clarity for Zone 1 and 2 test setup and methods. Additional guidance is also provided for identifying potential Zone 2 openings.

Additional information on these modifications is listed below.

Requirements for Adult Portable Bed Rails

The proposed changes to the standard are listed below, section by section. Modifications 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 changes to the standard.

In addition to complying with section 3.1 of ASTM F3186-17, comply with the following:

3.1.8: *Initial Assembly*, n— the first assembly of the product components after purchase, and prior to installing on the bed.

3.1.9: *Initial Installation*, n— 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).

3.1.10. Installation Component, n— component(s) of the bed rail that is/are specifically designed to attach the bed rail to 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).

Instead of complying to section 6.1.3 of ASTM F3186-17, comply with the following:

6.1.3. Permanently attached retention system components shall not be able to be removed without the use of a tool after initial installation 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.

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

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 shall be applied in addition to those requirements.

Instead of complying to section 6.3.3 of ASTM F3186-17, comply with the following:

6.3.3. Zone 3— The highest point on the cylinder of the test probe (see 7.2) shall not pass completely below the horizontal uncompressed plane of the mattress when tested according to 8.4.5. 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 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 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.¹

Instead of complying to section 6.4.1 of ASTM F3186-17, comply with the following:

6.4.1. Holes or slots that extend entirely through a wall section of any rigid material less than ~~14 0.375 in. (6.35 9.53 mm)~~ thick and admit a ~~5/8 0.210 in. (15.9 5.33 mm)~~ diameter rod shall also admit a ~~1 0.375 in. (25.4 9.53 mm)~~ diameter rod. Holes or slots that are between ~~8 mm 0.210 in (5.33 mm)~~ and ~~25 mm 0.375 in (9.53 mm)~~ and have a wall thickness less than ~~14 0.375 in. (6.35 9.53 mm)~~ but are limited in depth to ~~14 0.375 in. (6.35 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 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).

Instead of complying to section 6.5.1 of ASTM F3186-17, comply with the following:

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.

6.5.2: Determining Misassembled Product: A product covered by this specification shall be considered misassembled 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.

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

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.

¹ 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.

NOTE 2: 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. The current note numbers in the standard are redundant and should be updated. Adopting this note relative to section 7.1 would constitute "Note 2".

Instead of complying to section 7.2 of ASTM F3186-17, comply with the following:

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:

<http://www.fda.gov/MedicalDeviceRegulationandGuidance/GuidanceDocuments/ucm072662>.
<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 it can be purchased from NST Sales & Customer Service Office, 5154 Enterprise Blvd., Toledo, Ohio 43612, 800-678-7072, www.nst-usa.com. A video illustrating use of the test probe is available at the NST website (free registration required).

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>.

Instead of complying to NOTE 1 in section 8.4 of ASTM F3186-17, comply with the following:

NOTE 13: The tests described in this section are identical similar to those described in the referenced FDA Guidance Document. and in the NSA video

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. The current note numbers in the standard are redundant and should be updated. This note number was changed to 3 to align with other proposed changes.

Instead of complying to 8.4.3.4 of ASTM F3186-17, comply with the following:

Proposed § 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 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 and pass through 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.

Instead of complying to 8.4.4 of ASTM F3186-17, comply with the following:

8.4.4.3. Insert the 2.4 in- (60 mm) end of the cone perpendicular into the opening ~~from the longitudinal centerline of the mattress~~. 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.

8.4.4.4. If the test probe does not pull through freely using 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 ~~in both directions perpendicular to the rail~~.

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.

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 APBR 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.

Instead of complying to section 8.4.5.4 of ASTM F3186-17, comply with the following:

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.

(1) If the line on the face of the 4.7 in. (120 mm) end of the cone is above the surface of the mattress highest point of the uncompressed mattress, as shown in Figure 4a, the space passes the test.

(2) If the line on the face of the 4.7 in. (120 mm) end of the cone is at or below the surface of the mattress highest point of the uncompressed mattress, as shown in Figure 4b, the space fails the test.

Figure 4 Zone 3 test: (a) Pass, (b) Fail

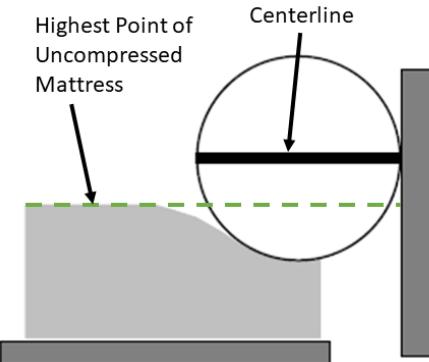


Figure 4a: Zone 3 Pass Criteria
(Centerline **above** highest point of uncompressed mattress)

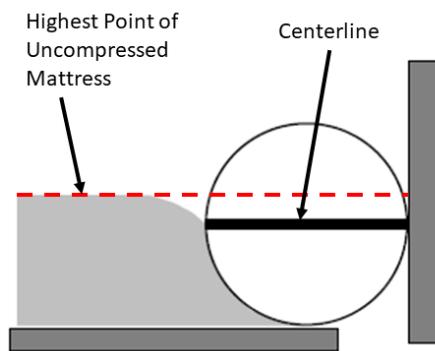


Figure 4b: Zone 3 Fail Criteria
(Centerline **below** highest point of uncompressed mattress)

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 proposed to assist testers in visualizing the test criteria.²

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

NOTE 4 - 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. The current note numbers in the standard are redundant and should be updated. Adopting this note would make it “Note 5” and make the current Note 2, “Note 6” instead.

Instead of complying to section 9.1.1.3, comply with the following:

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 either <2.4 in. (60 mm) or >12.5 in. (318 mm).

² 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.

Rationale: This 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 revision TG has agreed to these changes, and they will be incorporated into the next revision of the standard.

Instead of complying to section 9.2.5, comply with the following:

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, ~~and~~ 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 a grammatical edit and brings the warning language into alignment with similar language used in Section 9.2.6.

Instead of complying to section 9.2.7 of ASTM F3186-17, comply with the following:

9.2.7. At least one ~~conspicuous 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 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.

Instead of complying to section 11.1.1.3 of ASTM F3186-17, comply with the following:

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 G: Preliminary Regulatory Analysis



Memorandum

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

DATE: September 14, 2022

THROUGH: Alex Moscoso, Associate Executive Director,
 Directorate for Economic Analysis

FROM: Rodney R. Row, Economist,
 Directorate for Economic Analysis

SUBJECT: Adult Portable Bed Rail Preliminary Regulatory Analysis

Executive Summary

The U.S. Consumer Product Safety Commission (CPSC, or the Commission) is considering a draft proposed 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*, largely addresses known APBR hazards. However, CPSC testing conducted in 2018 and 2019, and then again in 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.

The market for APBRs is expected to grow at an average rate of 2.01 percent per year between 2024 and 2053 as a result of an aging U.S. population seeking 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 value¹ of the potential benefits is \$298.11 million.

Staff did not include injuries in its benefit-cost assessment because for many incidents involving injuries, there is not sufficient information to determine whether they would fall under the scope of this draft proposed rule. 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. However, staff does quantify and monetize the injuries in a sensitivity analysis as a potential upper limit to assess the benefits of this draft proposed rule.

The requirements of the draft proposed rule are expected to address 92 percent of deaths caused by entrapment and strangulation. However, CPSC staff assesses benefits under three scenarios derived from this baseline efficacy, estimating benefits at: 75 percent, 50 percent, and 25 percent of their potential value. Staff chose these scenarios as a stress test for the draft proposed rule to see how its benefits compared to its costs even under the pessimistic assumption that only one quarter, or 25 percent of

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.

benefits are achieved. At these rates, CPSC staff estimates the annualized benefits of the draft proposed rule to be \$200.24 million, \$133.49 million, and \$66.75 million, respectively. CPSC staff estimated annualized costs associated with the proposed requirements to prevent APBR hazards to be \$2.0 million. This results in net quantifiable net benefits of \$198.23 million, \$131.48 million, and \$64.74 million on an annualized basis.

CPSC staff's research and analysis demonstrate that CPSC staff's recommended requirements will decrease APBR deaths by reducing the occurrence of entrapment and other APBR hazards. CPSC staff concludes that the recommended requirements are technologically feasible and that the potential benefits of the draft proposed rule exceed the rule's costs. For these reasons, CPSC staff recommends that the Commission publish the draft notice of proposed rulemaking (NPR) for APBRs submitted with this briefing package.

1. Introduction

The CPSC is considering a draft proposed rule to establish a mandatory performance requirement and test procedure to reduce the risk of entrapment and other hazards associated with the use of APBRs. CPSC's draft proposed rule incorporates by reference ASTM F3186-17, with modifications, and mandates all APBRs sold in the United States must comply with the standard's performance requirements and testing.

On April 25, 2013, and on May 9, 2013, the CPSC received requests from two groups to initiate rulemaking under sections 8 or 9 of the CPSA to address reported hazards associated with APBRs. The requests were docketed in a single petition, CP 13-1. Also in 2013, ASTM formed the F15.70 subcommittee for Adult Safety Products and began developing a voluntary standard for APBRs. On April 29, 2014, the Commission voted to defer the petition to allow the voluntary standard process to continue until the APBR voluntary standard had been developed and evaluated by staff.

In 2017, ASTM published the voluntary standard ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. Staff's assessment indicated that ASTM F3186 – 17, with modifications, adequately addresses the hazards identified in the known incident reports. Despite the effectiveness of the standard, testing conducted by CPSC staff in 2018 and 2019, and again in 2021, found little-to-no evidence of market compliance with the voluntary standard. Accordingly, CPSC staff concludes that a mandatory rule that incorporates by reference ASTM F3186 – 17, with modifications, can reduce the risks of entrapment and other APBR hazards. These findings were presented to the Commission on March 15, 2022. The Commission voted unanimously (4-0) to grant Petition CP 13-1 and directed staff to draft an NPR.

1.1. Draft Proposed Rule

The proposed rule would establish a mandatory performance standard that all APBRs must meet to be sold in the United States. The requirement and test procedure of the draft proposed standard are detailed in (TAB F). In summary, the draft proposed rule incorporates by reference ASTM F3186, 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.

1.1.1 Effective Date

The proposed effective date for this draft proposed rule is 30 days after promulgation of the rule. Staff assesses that the APBR industry would be able to comply quickly with the rule because the modifications that would be needed to become compliant are not expected to require extensive product redesign. Staff also assesses that because firms would be able to comply quickly with the draft proposed rule, no economic costs are associated with a 30-day window for the effective date. Staff recommends seeking public comments on the 30-day window for the effective date.

1.1.2 Stockpiling

Given the 30-day window for the effective date, and the familiarity firms already have with ASTM F3186-17, which should allow them to comply quickly when the rule becomes effective, no stockpiling requirements were included in the draft proposed rule. Staff urges inviting public comments on stockpiling and supply chain information in connection with the draft proposed rule.

1.2. Preliminary Regulatory Analysis

Pursuant to section 9(c) of the CPSA, publication of a proposed rule must include a preliminary regulatory analysis containing the following:

- (5) a preliminary description of the potential benefits and costs of the proposed 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;
- (6) a discussion of the reasons why a standard submitted to the Commission was not published as the proposed rule;
- (7) a discussion of why a relevant voluntary safety standard would not eliminate or adequately reduce the risk of injury addressed by the proposed rule; and
- (8) a description of any reasonable alternatives to the proposed rule, together with a summary description of their potential costs and benefits and why such alternatives should not be published as a proposed rule.²

An overview of the APBR market can be found in section 2 of this memorandum. A preliminary description of the potential benefits and potential costs of the draft proposed rule can be found in sections 3 and 4 of this memorandum, respectively. An analysis of benefits relative to costs can be found in section 5 in this memorandum. Due to uncertainty in staff's estimates of nonfatal injuries, staff's benefits assessment only includes fatalities prevented by the draft proposed rule, and it compares them to costs incurred to comply with the rule. Analysis of the benefits with nonfatal injuries is included in a sensitivity analysis in section 5. No standard was submitted to the Commission. A discussion of the relevant voluntary safety standard can be found in section 6 of this memorandum. Finally, a discussion of the reasonable alternatives to the draft proposed rule can be found in section 7 in this memorandum.

² 15 U.S.C. § 2058(c).

2. Market Information

2.1. Number of Firms and Compliance with Voluntary Standards

APBR refers 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 this is not explicitly stated by the manufacturer. However, APBRs do not encompass all products that might be used for this function, for example, a chair. Nor does this product 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).

CPSC’s correspondence with select APBR manufacturers indicates that several firms rely on foreign importers to supply products marketed under the manufacturers’ brand names.³ CPSC staff has not determined whether the relationships between these firms are exclusive or if foreign importers also supply APBRs to other firms.

Information solicited from a non-statistical sample of firms in 2018, found no evidence that any APBR models complied with the voluntary standard, ASTM F3186 – 17. To assess industry compliance with the voluntary standard, CPSC staff tested sample populations of APBR models, first in 2018 through 2019, and again in 2021. In both instances, every tested APBR model failed at least one critical mechanical requirement and three warning/instruction requirements of the voluntary standard. Therefore, CPSC staff assesses there is not likely to be substantial compliance with the voluntary standard within a reasonable period.

In September and October 2021, EC staff conducted an online search that identified 12 firms supplying 65 distinct APBR models.⁴

2.2. Current Market Trends for Adult Portable Bed Rails

Retail prices for the identified APBR models ranged from \$38 to \$275. Based on an interview with one APBR manufacturer’s representative⁵ and market information from the identified APBR models, EC staff estimates that in 2021, the mean retail price is \$50 per APBR, total market revenues are approximately \$9 million, and the number of APBRs sold was approximately 180,000 units.

Based on data from online searches conducted by EC staff between 2014 and 2022, the number of APBR suppliers decreased approximately 25 percent in that period, and the number of APBR models

³ Correspondence subject to CPSA section 6(b) limitations on information sharing.

⁴ This includes one firm that has temporarily recalled all its products. Although EC staff conducted targeted online searches, it is possible that there are firms in the APBR market that EC did not identify.

⁵ In March 2021, EC staff conducted an informal interview with one APBR manufacturer’s representative. The interview confirmed EC staff’s assessment that there are about 10 firms with significant market share, with five or six of those collectively being dominant firms. The representative also confirmed that firms provided APBRs primarily through e-Commerce and retail sales, and that most APBRs are manufactured by foreign firms to specifications and designs developed by United States manufacturers and/or retailers.

offered decreased approximately 12 percent. Considering these market trends, CPSC staff assesses that the APBR market has been maturing over the past decade, with significant consolidation in the number of firms and models in the market. Staff assumes that the number of firms and models in use will tend to stabilize in future years around the values in 2022: 12 firms and 65 models. Staff also assumes that firms and models will continue to enter the market, but only to replace the firms and models that are exiting the market, in a way that the overall number of firms and models in use will stay at these steady state volumes for the industry.

APBR sales had been steadily increasing, but they peaked in 2018, at approximately 240,000 units sold in that year. Since then, sales have begun to decline. According to a manufacturer's representative, the primary cause of the decline in APBR revenues and units sold is the participation of three major APBR firms in CPSC voluntary recalls. Contributing factors may include supply chain issues and a decline in consumer confidence related to the SARS-CoV-2 pandemic. Based on the feedback from this interview, staff assumes a 5-year recovery period for the APBR market to return to its "peak" level in 2018. Figure G.1 displays estimated APBR sales for the period 2003–2019.

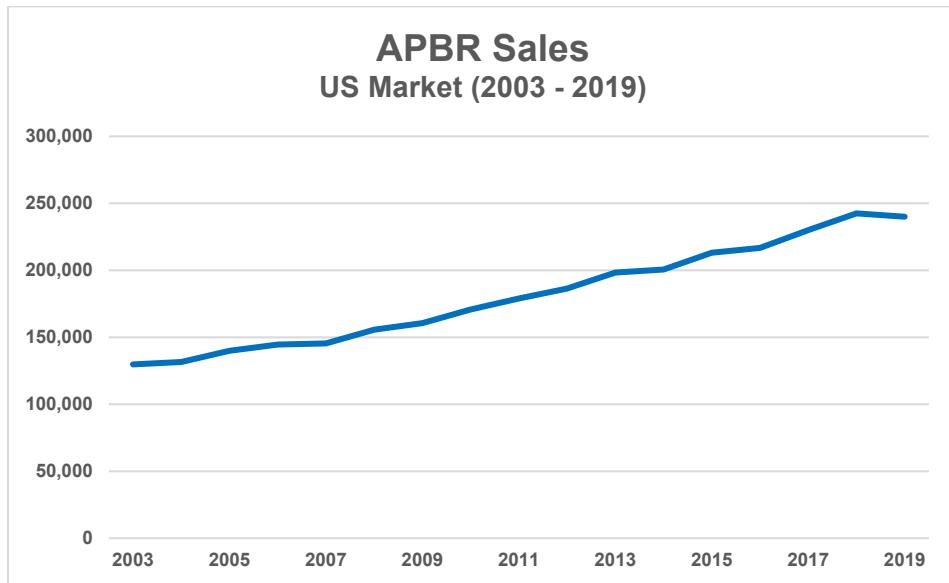


Figure G.1: Estimated APBR Sales

2.3. Future Market Size for Adult Portable Bed Rails

The APBR industry's target user skews heavily to the elderly because it is the demographic more likely to use home health care products, like APBRs. To forecast the number of APBRs beyond 2024, staff estimated the growth of the APBR industry's target user population. EC staff also captured a multiplier, which measures how much faster the APBR industry grows with respect to population-driven growth. This multiplier captures the rate of accelerated growth, presumably due to rising healthcare costs that have pushed many people to opt for home health care for the elderly and the disabled, above and beyond the growth purely expected as a result of annual increases in the target population.

Staff initiated the estimation of the APBR target population by collecting U.S. Census Bureau (Census) population projections. Then staff focused on three age groups,⁶ and estimated the annual growth rates over time for each these groups. Also, using incident data, staff estimated the composition of the target APBR population, as follows: Under 64 years of age, 15.7 percent; between 65 and 84 years of age, 34.1 percent, and 85 years and older, 50.2 percent. Staff estimated the average annual growth of the APBR population by multiplying the growth rate of each age group in the Census projections⁷ by the share each group represents in the APBR target population.

To estimate the growth multiplier, CPSC collected data from the Census and the U.S. Department of Health and Human Services regarding the U.S. expenditure by health segment from 2006 to 2018, as well as the Personal Consumption Expenditure (PCE) index on health-related expenditures from the Bureau of Economic Analysis, to remove health inflation from the previous estimates. The average nominal growth rate in Home Health Care expenditure was estimated at 5.6 percent, after removing average inflation in the sector of 1.1 percent. Staff estimated the real growth rate of the Home Health Care segment to be 4.4 percent, on average, during this period. The ratio of the Home Health Care segment growth rate and average APBR annual population growth of 2.94 percent over the same period is approximately 1.5. Staff applied this ratio to the average APBR population growth to forecast the growth in the number of APBRs sold during the entire period of analysis.

3. Preliminary Regulatory Analysis: Benefits Assessment

Staff conducted the preliminary 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 draft proposed 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 forecasted the number of expected deaths for a 30-year study period and converted the value of prevented casualties into monetary terms using the Value of Statistical Life (VSL) for deaths.

Staff used a 30-year study period to assess the benefits of the draft proposed rule. Staff assumes, for the purpose of this analysis, that the rule would go into effect in 2024; 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 draft proposed rule. Staff then converted the aggregate benefits over the 30-year study period into annualized and “per-product” outputs. 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.⁸ A per-product metric expresses the benefits from the rule in one unit of product. This metric is helpful when assessing the

⁶ Staff separated the Census Bureau population forecasts in three age groups: Under 64, 65 to 84, and 85 and Older.

⁷ Staff estimated annual average population growth rates for every calendar decade. The average APBR population growth averages 2.87 percent before 2030, declines to an average of 2.56 percent from 2030 to 2040, with further declines to 1.37 percent and 0.58 percent for the periods 2040 to 2050 and 2050 to 2053, respectively.

⁸ 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.

impact in marginal terms, for example, comparing benefits to an increase in retail price or marginal increase in cost of production per-unit. Staff presents both these metrics to convey a holistic perspective of the impact of this draft proposed rule.

3.1. Uncertainty

Uncertainty is inherent in any estimate or forecast of future events. This regulatory analysis estimated future benefits and costs associated with promulgating the draft proposed rule. Staff performed this regulatory analysis using the best readily available information and data. When data are not available, staff made assumptions based on subject matter expert feedback. Even in the cases where data is available, the data are historical, and it is not a certainty that the future will follow historical patterns. The farther into the future, the more uncertain the estimate. However, staff applied statistical methods to mitigate the uncertainty, to the extent possible. This section describes the specific uncertainty associated with this regulatory analysis above the typical cost-benefit analysis.

There is an increased level of uncertainty in the benefits assessment, due to the lack of available information for incidents resulting in injuries, to determine whether they would fall under the scope of this draft proposed rule. 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. Given the heightened level of uncertainty with injuries, staff does not include them in its benefit-cost assessment for this draft proposed rule. However, staff does quantify and monetize injuries in a sensitivity analysis in section 5 as a potential upper limit to the benefits of this draft proposed rule. Staff seeks public comment on the availability of incident data of entrapment and strangulation events that result in injury due to APBRs.

3.2. Deaths Related to APBR Hazards

Staff identified 158 deaths from entrapment and strangulation that occurred from 2010 through 2019.⁹ 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 draft proposed rule. To forecast deaths into the future, staff used death rates per million APBRs with its forecast of APBRs in use throughout the study period. Staff assumed deaths would stay the same as the average rates observed between 2010 to 2019: 31.9 deaths per million APBRs. Staff forecasted APBRs in use using the population breakdown by age of APBR users, adjusted for population demographics and the growth of home healthcare spending.

Figure G.2 below displays the estimate of the number of deaths from APBRs in the period from 2010 through 2053 in the baseline scenario, which assumes the draft proposed rule does not go into effect.

⁹ Staff chose the period of 2010 through 2019 to base its rate of fatalities per product because it was the most recent 10-year window where staff is confident all or nearly all incidents have been reported.

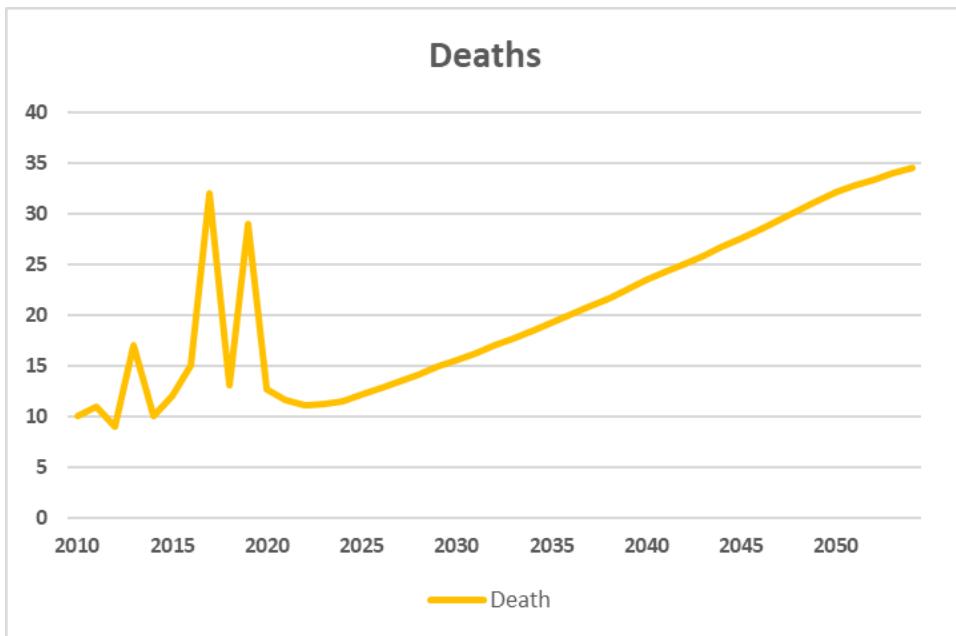


Figure G.2: Number of Deaths from APBR Hazards ¹⁰

To estimate the societal costs of entrapment and strangulation-related deaths, staff applied the VSL. VSL is an estimate used in benefit-cost analysis to place a value on reductions in the likelihood of premature deaths (OMB, 2003). 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 (OMB, 2003). This is a “willingness to pay” methodology that attempts to measure how much individuals are willing to pay for a small reduction in their own mortality risks, or how much additional compensation they would require to accept slightly higher mortality risks. For this analysis, staff applied estimates 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.¹¹ Staff multiplied the VSL by the number of forecasted deaths throughout the study period to calculate societal costs of deaths from entrapment and strangulation in the absence of the draft proposed rule. Figure G.3 displays these costs over the study period.

¹⁰ This does consider all recall efforts, but it assumes no new rule is implemented.

¹¹ In 2008, the EPA estimated the value of a 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 by the Bureau of Labor Statistics, and rounded it to the nearest hundred thousand. The adjustment is as follows: $\$7.9M \times (278.802/210.228) = \$10.477M$, which is then rounded to \$10.5M.

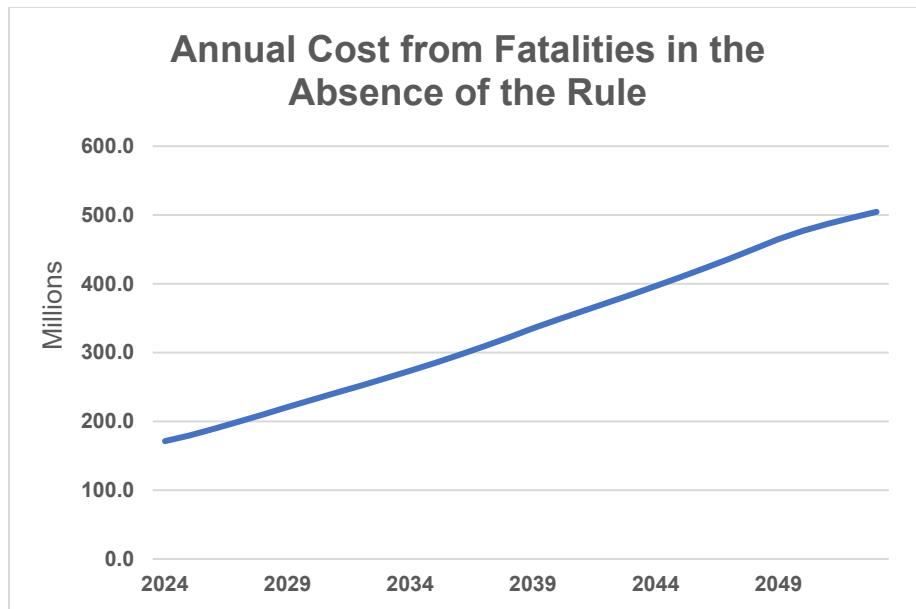


Figure G.3: Cost from Fatalities

3.3. Benefits from the Draft Proposed Rule

The total estimated societal cost of deaths in the absence of the draft proposed rule would be \$5.84 billion over the study period (2024-2053), discounted at 3 percent annually. However, staff needed to take additional steps to calculate how much of the potential societal costs the draft proposed rule would mitigate. The draft proposed rule would not immediately mitigate all the deaths from known hazards because there would still be noncompliant APBRs in use in the initial years of the study period. To account for this, staff applied the percentage of compliant APBRs (those purchased in or after 2024) in the market¹² to the total potential societal cost of deaths for each year in the study period. After this adjustment, staff estimated that \$5.23 billion in societal costs, over the 30-year study period, could be avoided if the CPSC promulgated the draft proposed rule. However, this estimate assumes that all compliant APBRs would have a 100 percent effective rate.

Staff had to consider the expected level of efficacy from the draft proposed rule, even among compliant APBRs. Very few standards have a 100 percent efficacy rate. At a baseline level, the requirements of the draft proposed rule may eliminate up to 92 percent of deaths associated with entrapment and strangulation. Additionally, the effectiveness of the draft proposed rule depends, to some extent, on consumers installing the product correctly. The draft proposed rule provides significant improvements designed to help consumers; however, there may still be some deaths resulting from improper installation or installation on mattresses of inappropriate thickness for the product. CPSC staff cannot provide a precise measurement of effectiveness of the draft proposed rule.

Staff chose to assess benefits under the scenarios of 75 percent, 50 percent, and 25 percent of the baseline efficacy rate. Staff chose these scenarios as a stress test for the draft proposed rule, to see how its benefits compared to its costs, even under the pessimistic assumption that only one quarter of the potential benefits would be achieved, or 25 percent of the baseline efficacy rate. As shown in Table G.1.,

¹² Percentage of compliant APBRs for Year 20XX = Number of compliant APBRs (those purchased in or after 2024) in 20XX ÷ [Number of compliant APBRs in 20XX + Number of noncompliant APBRs (those purchased before 2024) in 20XX].

the 75 percent, 50 percent, and 25 percent rates would reduce potential benefits to \$3.92 billion, \$2.62 billion, and \$1.31 billion, respectively, for the 30-year study period.

Table G.1 Aggregate Benefits Discounted at 3%

Potential Benefits (\$ billions)	Portion of Benefits Achieved over the Baseline Efficacy Rate of Redesigned APBRs		
	75%	50%	25%
Benefits (2024-2053)	\$3.92	\$2.62	\$1.31

3.4. Annualized and Per-APBR, In-Use Benefits of the Draft Proposed Rule

Staff then converts the aggregate benefits over the 30-year study period into annualized and “per-product” metrics. An annualized metric 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 are front-loaded for only one of them.

Table G.2 presents the findings from this benefits assessment from an annualized perspective.

Table G.2: Annualized Benefits, Undiscounted and Discounted at 3%

Annualized Benefits (\$ millions)	Portion of Benefits Achieved over the Baseline Efficacy Rate of Redesigned APBRs		
	75%	50%	25%
Undiscounted	\$226.20	\$150.80	\$75.40
Discounted at 3%	\$200.24	\$133.49	\$66.75

Per-product metrics express the benefits from the rule in one unit of product. This metric is helpful when assessing the impact in marginal terms; for example, comparing the benefit and costs, and the effects on the price. To estimate the benefit per product, staff divided the annualized benefits (undiscounted and discounted) by the average number of units to calculate the benefits per-product.

Table G.3 presents the findings from this benefits assessment from a per-product perspective.

Table G.3: Per-Product Benefits, Undiscounted and Discounted at 3%

Per Product Benefits (\$)	Portion of Benefits Achieved over the Baseline Efficacy Rate of Redesigned APBRs		
	75%	50%	25%
Undiscounted	\$573.66	\$382.44	\$191.22
Discounted at 3%	\$331.78	\$221.19	\$110.59

4. Preliminary Regulatory Analysis: Cost Analysis

This section discusses the costs the draft proposed rule would impose on industry and the market. There are three cost components discussed under this cost section: the cost of implementing an APBR fix 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 fix.

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 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.¹³

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 modifications as proposed by staff. Staff assumed that 100 percent of manufacturers adopt this solution and estimated the full cost of the draft proposed 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 to comply with ASTM F3186 – 17, as well as the cost of producing the redesigned APBR.¹⁴ The increased cost is then passed on to wholesalers. The subcategories of costs for implementing an APBR entrapment and strangulation hazard solution are:

- Cost of Redesigning Existing APBR Models and New Designs

Manufacturers incur design costs that include redesigning existing APBR models, and designing APBR models in the future, to comply with the ASTM F3186. This standard has 17 performance requirements, with modifications specified by the proposed rule.

Manufacturers will have to redesign existing APBR models if they wish to continue selling these models to consumers. Manufacturers, therefore, would have to allocate funds to produce solution designs and adapt existing APBR models. Manufacturers would likely incur expenditures in design labor, design production, design validation, and compliance testing. These subcategories of cost are discussed below.

- Cost of Design Labor

This is the cost to compensate model designers employed by the manufacturer (or a third-party designer) for the time to produce a blueprint of the redesigned APBR model

- Cost of Design Production

This is the cost of materials and labor required to fabricate prototypes of the APBR model

- Cost of Design Validation

This is the cost 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.

¹³ 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.

¹⁴ The draft proposed rule does not require manufacturers to update or replace APBRs manufactured or sold before implementation of the proposed APBR mandatory standards.

- Cost of Compliance Testing

This is the cost of conducting formal, third-party compliance testing to verify compliance with the requirements of the new APBR mandatory standards. Compliance testing is customarily conducted through third-party testing.

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

- Cost of Manufacturing the Redesigned APBR

Manufacturers incur costs to produce the redesigned APBR.¹⁵ Manufacturers would likely incur expenditures to purchase the required materials to fabricate the APBR and to produce the APBR. Staff assumed that the production cost of the solution closely matches that of existing APBRs. Therefore, the incremental production cost is negligible, and the estimates in this subcategory focus exclusively on the incremental cost of materials required to manufacture APBRs compliant with the draft proposed rule.

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

Deadweight loss¹⁶ 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 draft proposed rule. The requirements for APBRs from the draft proposed rule increase the marginal cost of production for manufacturers.

Manufacturers can transfer some, or all, of the increased production cost to consumers through price

¹⁵ The APBR can be fabricated in-house by the manufacturer or by a third-party contractor hired by the manufacturer.

¹⁶ The deadweight loss (DL) is estimated as $DL = (Q_0 - Q_1) \frac{\Delta C_p}{2}$, where Q_0 is the expected market volume absent the proposed rule, Q_1 is the expected market volume after the impacts of the rule, and ΔC_p is the average long-term change in the cost of production. Q_0 - the expect market volume absent the proposed rule- is forecasted for each year in the time horizon of the analysis using staff estimates of the APBR market trend based on the U.S. Census Bureau estimates of Q_1 - the expected market volume after the impacts of the rule- is estimated from Q_0 , the average price, price elasticities of demand and supply, and the change in the cost of production using the following formula: $Q_1 = Q_0 \left(1 + \frac{\Delta C_p}{P_0} \frac{\varepsilon_s \varepsilon_d}{\varepsilon_s - \varepsilon_d}\right)$. The average long-term variable cost of production is estimated spreading large one-time costs--such as the cost of redesigning all existing APBR models within a short-period of time--over the planning horizon of the analysis and adding this estimate to the average annual short-term variable cost. To assess the effective market impact of the proposed rule, ΔC_p also includes a markup of 38 percent to cover the wholesalers' distribution costs (see Goldberg, Pinelopi 1995).

increases.^{17, 18} 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. For this analysis, staff estimated deadweight loss for each year the draft proposed rule is expected to have an impact on marginal cost and market price. The estimate assumes that producers would base their production decisions on the long-term impacts of the rule on their cost of production.

4.1. The Cost of Redesigned APBRs

This subsection presents cost estimates for manufacturers to produce redesigned APBRs that comply with the draft proposed rule.

4.1.1 Cost of Redesigning APBR Models

Staff estimated the cost of redesigning all existing APBR models by multiplying the unit cost of redesigning each existing model by the number of APBR models to be redesigned.

4.1.1.1 Unit Cost of Redesigning APBR Models

Staff estimated the unit cost of redesigning existing APBR models in two steps. First, staff estimated the unit cost of redesigning a single or “first” model before achieving any cost improvements.¹⁹ Second, staff developed a cost improvement curve to account for economies of scale in the redesign of many models, and the efficiency gains from specialization and learning.

Staff estimated the unit cost of the “first” model using information from CPSC technical staff and APBR manufacturer interviews. CPSC staff produced estimates of the cost of redesigning an APBR at each stage of the design process:

- Cost of Design Labor

Staff estimated it would require a team of two designers 1 month to produce a final blueprint of an APBR model design that complies with the requirements of the draft proposed rule, or approximately

¹⁷ An increase in the marginal cost of production in a competitive market normally is followed by an increase in the prices at which products are traded. The portion of the increased production costs that are paid for by consumers through higher market prices depend on the price responsiveness of demand and supply of the product. The price responsiveness of demand and supply are measured by the price elasticity of demand and supply, respectively. Price elasticity is a measure of how responsive the volume of product demanded or supplied in the market is to a change in the price of such product. Price elasticity is estimated as the ratio of the percentage change in the volume demanded or supplied as a result of a percentage change in price, or $\varepsilon = \frac{\Delta\%Q}{\Delta\%P}$. For most products, the elasticity of demand is a negative number that indicates price increases lead consumers to demand less of the product; while the elasticity of supply is a positive number that indicates an increased willingness to offer products in the market as the price of the product increases.

¹⁸ More precisely, the change in the market price of equilibrium ($P_1 - P_0$) that follows an increase in production costs (C_p) in a competitive market can be estimated as $P_1 - P_0 = \Delta C_p \left(\frac{\varepsilon_s}{\varepsilon_s - \varepsilon_d} \right)$, where ε_s is the elasticity of supply and ε_d is the elasticity of demand. In a market with a completely inelastic demand ($\varepsilon_d = 0$), producers can transfer the entire change in the cost of production to consumers through price increases. The highest the elasticity of demand, the lowest the portion of the increased production costs that can be transferred to consumers through price increases.

¹⁹ The design costs per APBR model are expected to decrease as the number of redesigned APBR models increases (i.e., fixed costs spread over additional models, increased level of experience redesigning APBR models).

a total of 347 hours.²⁰ The average compensation rate of a designer is \$63.96 per hour²¹ for a total cost of \$22,536 per redesigned model in 2021 dollars.

- Cost of Design Production

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

Staff estimated 1 day of validation testing would be required per each redesigned APBR model at a cost of \$21,423 per model.²²

- Cost of Compliance Testing

Staff estimated that, on average, four APBR models would be tested per day at a cost of \$5,356 per redesigned model.²³

By aggregating all the unit costs, staff calculated that the total “first” model cost per redesigned APBR model is \$49,915. This estimate is before the consideration of cost improvements from economies of scale and learning in model design.²⁴ To account for cost improvements, staff used a cost improvement curve. The improvement curve assumes that every time the number of units produced doubles, there is a 2.7 percent reduction in the average redesign cost per APBR model.²⁵ Under these assumptions, when manufacturers redesign 65 APBR models in a particular year, the average redesign cost per model in that year would decline to about 85 percent of the “first” model (overall a cost of \$42,239 per model).

²⁰ CPSC staff estimated it would take up to 2-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 (2-person months).

²¹ 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 2-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>).

²² Subject matter expert input was \$20,000 in 2020 dollars. Staff inflated to 2021 dollars using the Consumer Product Index (CPI-U).

²³ Subject matter expert input was \$5,000 in 2020 dollars. Staff inflated to 2021 dollars using the Consumer Product Index (CPI-U).

²⁴ The traditional definition of “learning curves”—or more properly in this case “cost improvement curves”—is centered on the observation that the cost per unit is reduced by a certain percentage every time the number of units produced doubles. The most cited models are derived from T.P. Wright (1936 - cumulative average unit cost) and J.R. Crawford (1944 - specific unit cost). The functional form in both models is: $C(X) = AX^\alpha$, where $C(X)$ is the cost function at level of production X , A is the cost of the first (theoretical) unit, X is the number of units produced, and α is the slope. In Wright's model, $C(X)$ is the cumulative average cost (the form used here); while in Crawford's model, $C(X)$ is the cost of the last unit produced.

²⁵ For simplicity, staff assumed each of the redesign cost categories discussed here follow the same cost improvement trend. The cost improvement curve -or learning curve- used by staff has the following functional form: $C(X) = AX^\alpha$, where $C(X)$ is the cumulative average cost per unit at each level of production, A is the cost of the first (theoretical) unit, X is the number of units produced, and α is the slope. A 2.7% cost improvement implies the value of the slope α is -0.04 (given the function form a doubling in production results in a cost improvement of $1 - 2^{-0.08} = 2.73\%$). Cost improvement curves are usually estimated econometrically using available cost / manufacturing data; however, in the absence of such information, CPSC selected the cost improvement percentage based on cost improvement curves from similar activities and derived the parameters.

Since the model redesign cost varies with the number of models redesigned each year, it is pertinent to discuss—before the discussion of unit cost per model—the forecasted number of models.

4.1.1.2 Number of Redesigned APBR Models

Figure G.4 shows the estimated number of new models sold during the period 2003 through 2019, as well as an estimate of the total number of APBR models in use by consumers during the same period.²⁶ For instance, in 2019, a total of three new models were introduced; the same year an estimated 74 models were in use by APBR owners/users.

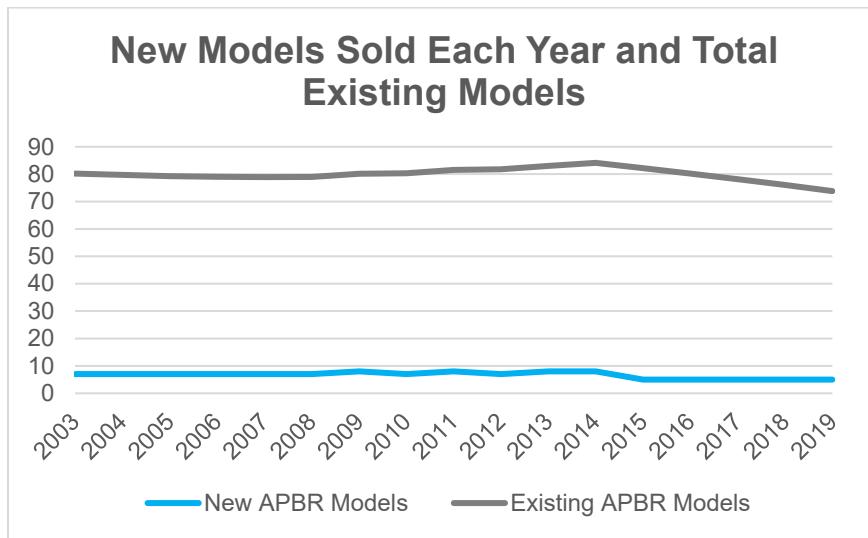


Figure G.4: Number of Models for Sale and Total Models in Use

Staff forecasted the number of new models every year in the 30-year study period by using exponential smoothing to forecast²⁷ the number of new models produced.²⁸ Next, staff used the forecast of the number of models to estimate how many models would be in use in every year in the 30-year study period by applying a statistical distribution of model life rates²⁹ based on the average number of years a model is offered for sale in the market for new APBRs.

²⁶ Staff estimated the number of models sold and in use by applying exponential smoothing to staff's observations in 2014, 2018, 2021, and 2022.

²⁷ Exponential smoothing is a time series-forecasting technique that produces projections that are weighted averages of past observations, with weights that decay exponentially as the observations get older. More recent observations, therefore, are assigned heavier weights and carry more importance in the forecast.

²⁸ CPSC staff developed two sets of forecasts, the first set (or baseline forecast) assumes no impacts from the proposed rule, while the second set considers a small reduction in the number of models resulting from the market impacts of introducing the draft proposed rule. Because the cost impacts of the draft proposed rule are relatively small, the difference between the two sets of forecasts is small and not noticeable in the chart below.

²⁹ A two-parameter gamma distribution was used to forecast model survival rates with a shape parameter of 11 and scale parameter of 1. These distribution parameters are consistent with a mean model duration of 11 years, which staff considered representative of durable medical equipment, such as APBRs. The distribution of model life rates mentioned above is the converse of the distribution of model survival rates.

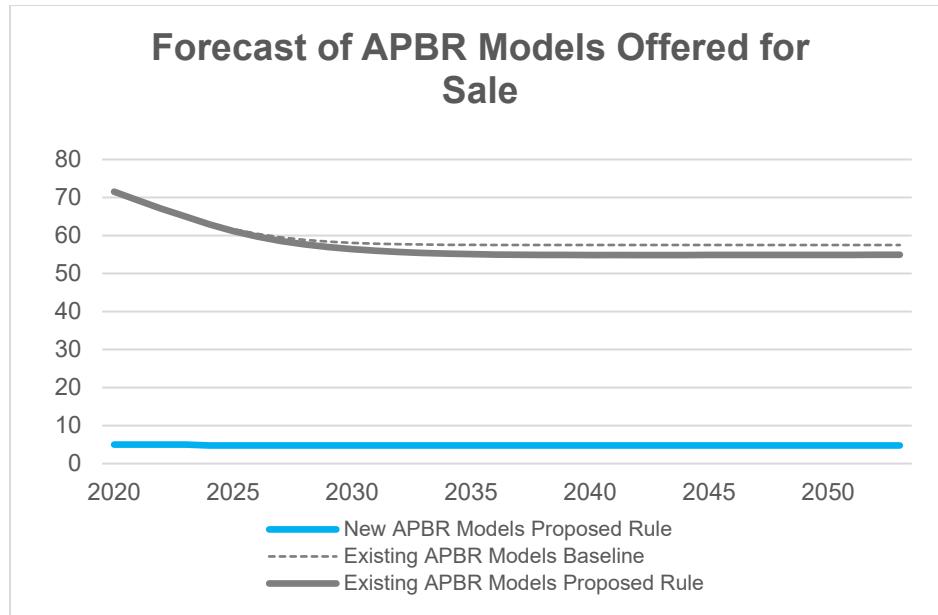


Figure G.5: Forecast of Models for Sale and Total Models in Use

Figure G.5 shows the number of new models sold and the number of models in use during each year during the 30-year study period. In 2023, a year before the assumed implementation of the draft proposed rule, the number of APBR models in use is 65. This is the number of existing models that manufacturers would be required to redesign.³⁰ Staff assumed for the purpose of this analysis, that redesign of all existing models would occur in the first year, 2024. Staff welcomes public comment on the redesign process of APBR models and the speed with which this can occur.

Due to cost improvements associated with redesigning a relatively large number of APBR models (65), staff estimated the initial cost per model redesign to drop from \$49,915 to an average of \$42,239 during the year. Therefore, the industry incurs a redesign cost of \$2.75 million in 2024, equivalent to a present value of \$2.59 million.

4.1.2 Cost of Manufacturing APBRs Compliant with the Draft Proposed Rule

Staff estimated the cost of producing redesigned APBRs by multiplying the unit cost of each APBR manufactured by the number of APBRs manufactured.

4.1.2.1 Unit Cost of Compliant APBRs

Staff estimated the unit cost of the redesigned APBRs in two steps. First, EC staff used unit costs informed by CPSC Laboratory Sciences staff to estimate the additional cost of production and materials to be the cost of the “first” redesigned APBR in the cost improvement curve.³¹ Second, EC staff produced

³⁰ Starting on the year of implementation of the rule (expected in 2024), all new models will have to comply with new standard in order to be sold to new/prospective APBR customers.

³¹ The traditional definition of “learning curves”—or more properly in this case “cost improvement curves”—is centered on the observation that the cost per unit is reduced by a certain percentage every time the number of units produced doubles. The most cited models are derived from T.P. Wright (1936 - cumulative average unit cost) and J.R. Crawford (1944 - specific unit cost). The functional form in both models is: $C(X) = AX^\alpha$, where $C(X)$ is the cost function at level of production X , A is the cost of the first

an estimate of the average additional cost per unit once manufacturers started producing compliant APBRs in large quantities. Staff adjusted the cost improvement curve to render estimates in line with the subject matter experts in CPSC's Directorate for Engineering who assessed what would be the cost after economies of scale take effect.

Staff estimated the incremental cost of the "first" redesigned APBR to be \$14.49.

Staff calibrated a cost improvement curve that assumes each time the number of APBRs produced doubled, there is a 5.45 percent reduction in the average APBR manufacturing cost.³² When 300,000 APBRs are produced, the average cost drops to \$5.23 per redesigned APBR, and when 400,000 APBRs are produced, the average cost drops to \$5.11 per redesigned APBR. In most years, sales of new APBRs are expected to be greater than 300,000 units. The average APBR cost, as shown in the chart, depends on the number of sales per year.

4.1.2.2 Number of APBRs Sold

Staff estimated the number of APBRs sold by adjusting sales and revenue estimates for the period 2018–2022, using U.S. Census Bureau population projections, the estimated composition of the target APBR population, and health care expenditure growth rates (see section 2.3 of this Tab for a detailed discussion). Staff also estimated the number of APBRs in use by applying a 2-parameter gamma distribution to the APBR population to forecast APBR survival rates.³³ Figure G.6 shows the estimated number of new APBRs sold during the period 1998 through 2019, as well as an estimate of the total number of APBRs in use during the same period. During 2019, firms sold an estimated 240,000 new APBRs to consumers, and the number of APBRs in use during the same year is estimated to be 588,000.

(theoretical) unit, X is the number of units produced, and α is the slope. In Wright's model, $C(X)$ is the cumulative average cost (the form used here); while in Crawford's model, $C(X)$ is the cost of the last unit produced.

³² A 5.45 percent cost improvement implies the value of the slope α is -0.08 (given the function form a doubling in production results in a cost improvement of $1 - 2^{-0.08} = 5.45\%$).

³³ A two-parameter gamma distribution, with shape parameter 2 and scale parameter 1 corresponding to a mean APBR product life duration of 2 years, was used to forecast APBR survival rates. The distribution of product life rates mentioned is the reciprocal of the distribution of survival rates.

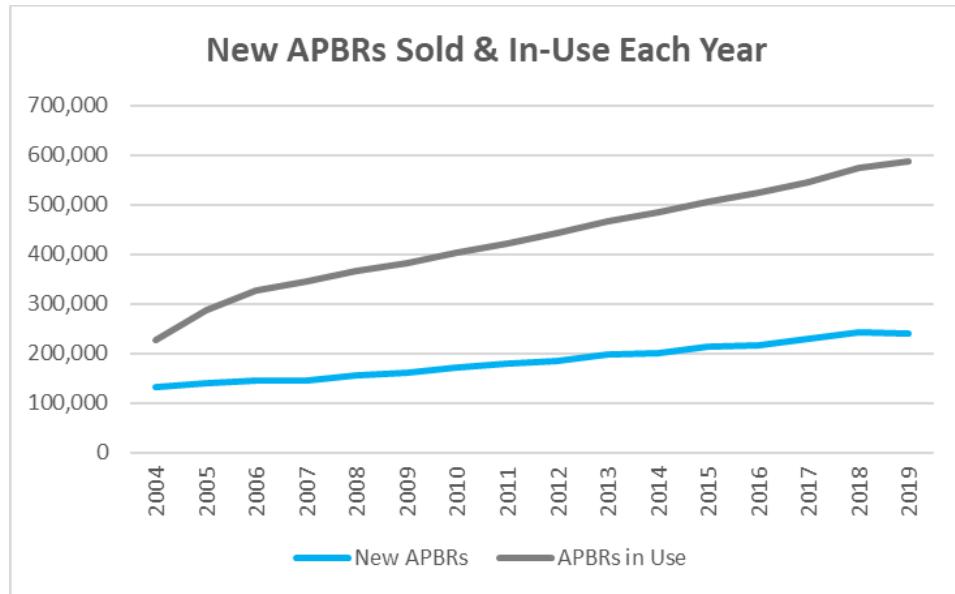


Figure G.6: Estimated Number of APBRs Sold and In-Use Each Year

Staff applied the same techniques used to estimate the number of APBRs sold and in use to forecast the number of new APBR sales units in use within the 30-year study period.³⁴ Figure G.7 shows APBRs sales relative the baseline (in the absence of the proposed rule) during the 30-year study period, 2024 to 2053.

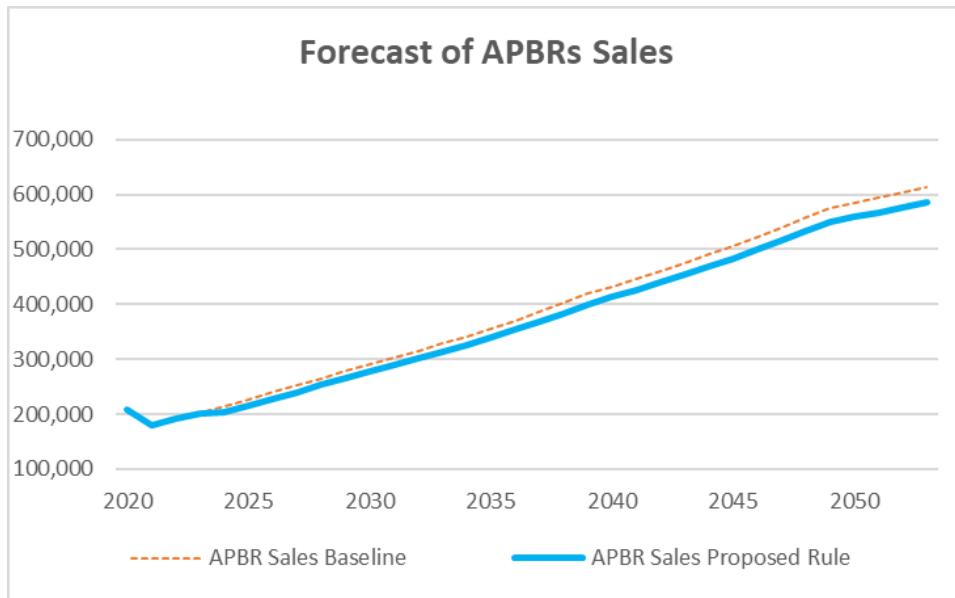


Figure G.7: Forecast of APBR Sales

Figure G.8 shows the number of APBRs in use relative to the baseline (in the absence of the proposed rule) during the 30-year study period, 2024-2053.

³⁴ CPSC staff developed two sets of APBR forecasts, the first set (or baseline forecast) assumes no impacts from the proposed rule, while the second set considers a small reduction in the number of APBRs from the market impacts of the proposed rule.

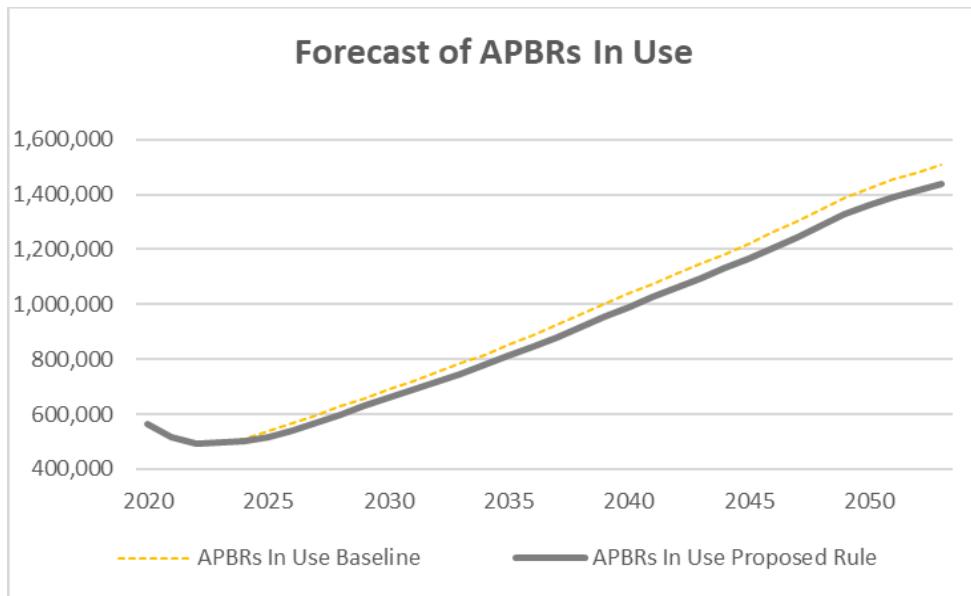


Figure G.8: Forecast of APBRs In-Use

Figure G.9 shows the number of APBRs produced over time and the corresponding (undiscounted) incremental cost per unit.

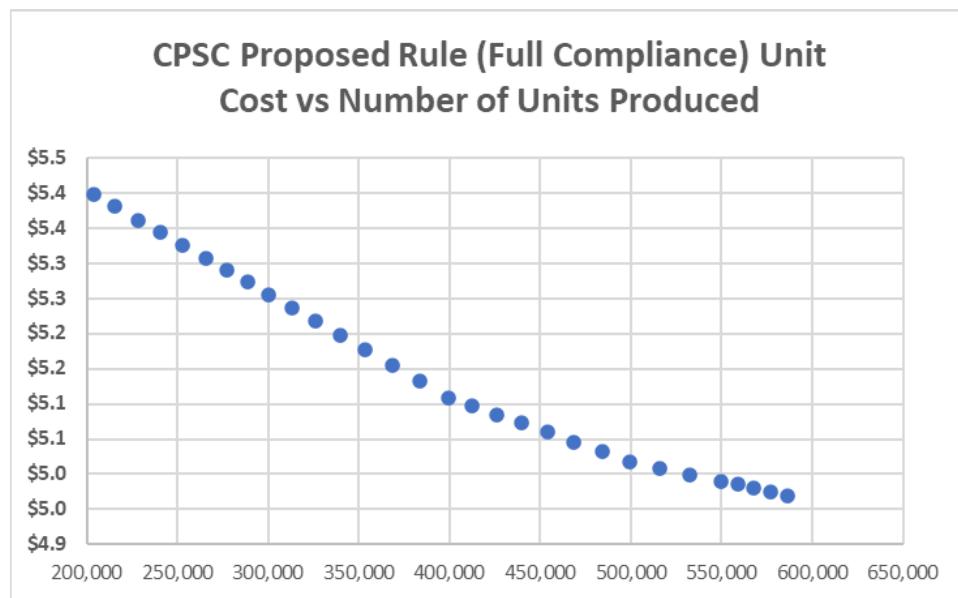


Figure G.9: Incremental APBR Unit Cost by Production Volume

Over the 30-year study period, the estimated average undiscounted incremental production cost is \$5.11 per redesigned APBR. The total cost of producing APBRs compliant with the draft proposed rule is \$60.43 million over the 30-year study period. The equivalent present value at a 3 percent discount rate is \$35.65 million. Table G.4 summarizes these costs:

Table G.4: Additional Cost of Manufacturing Rule-Compliant APBRs

Average Incremental Cost per Redesigned APBR (\$)	Millions of New Redesigned APBRs	Total Cost of Redesigned APBR (\$M)
2024 – 2053	\$5.11	11.83
Present Value		\$35.65

The total cost of implementing the APBR fix to address entrapment and strangulation hazards is summarized in the Table G.5:

Table G.5: Redesign and Production Cost

Cost of Redesigned APBR Fix	Average Cost per APBR (\$)	Millions of New APBRs	Cost of Redesigned APBRs (\$M)	Present Value (\$M)
Cost of Redesigning Existing Models	\$0.23	11.83	\$2.75	\$2.59
Cost of Producing Redesigned APBRs	\$5.11	11.83	\$60.43	\$35.65
Cost of APBR Fix	\$5.34	11.83	\$63.17	\$38.24

4.2. Dead Weight Loss

To produce an estimate of the market-related losses to producers and consumers, staff estimated the annual average increased cost of production, the resulting increase in average prices, and reduction in volumes traded in the APBR market. Staff then used those estimates to calculate the deadweight loss for each year in the 30-year study period.

Staff assumed that manufacturers would increase prices in response to changes in the average long-term variable costs of producing APBRs. Staff calculated the expected changes in long-term variable costs by spreading the spikes in short-term costs from complying with the draft proposed rule, as shown in Figure G.10:

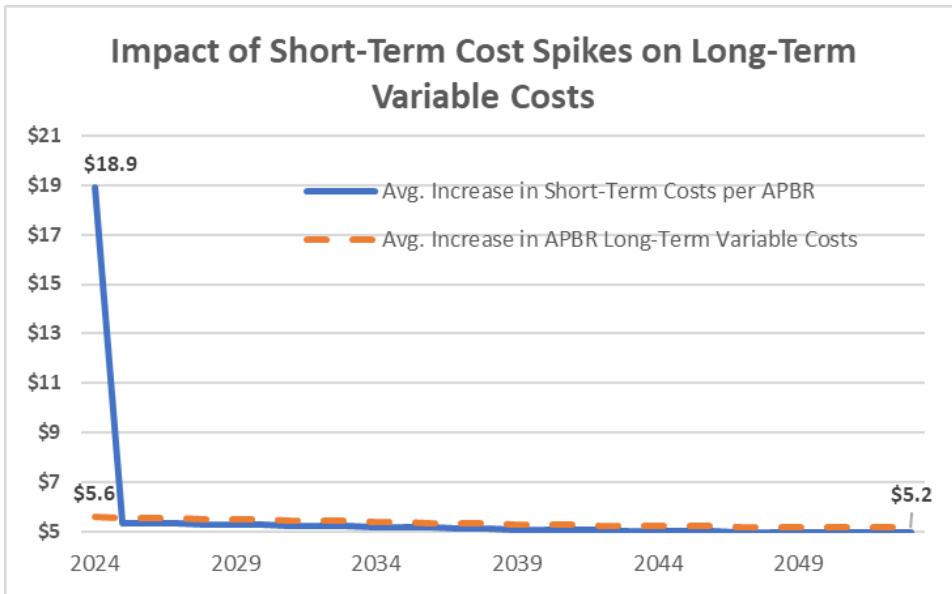


Figure G.10: Long-Term Impact of Short-Term Cost Spikes

Staff augmented the average long-term cost per APBR shown in Figure G.11 by a 38 percent³⁵ wholesaler distribution markup. This simulates the market impact that the draft proposed rule has on the APBR supply curve.

Staff adjusted the average annual prices from the period 2004 to 2019 to constant 2021 dollars³⁶ and then forecasted prices for the 30-year study period using exponential smoothing. The following charts in Figure G.11 show the price impact of the draft proposed rule, relative to baseline conditions (assuming no draft proposed rule in effect) forecasted through 2053.

³⁵ The effective market impact is likely to include a markup to cover the wholesalers' distribution costs. The 38 percent markup comes from Goldberg 1995.

³⁶ Prices were brought forward using the Consumer Price Index for All Urban Consumers from the Bureau of Labor Statistics.

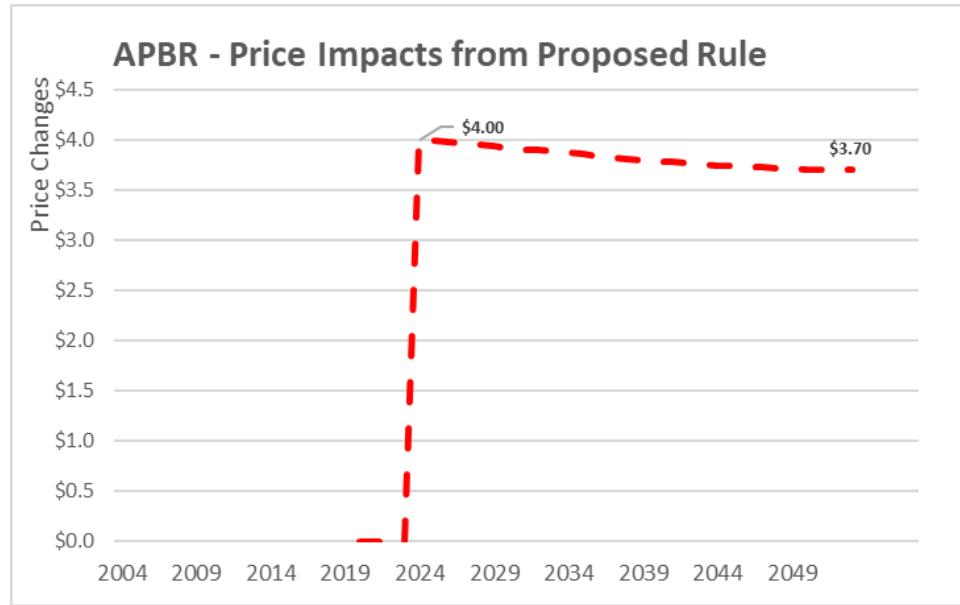


Figure G.11: Price Impacts from the Rule

The impact of the rule on the APBR price is relatively large, representing an approximate 8 percent increase in the average market price.³⁷ Consequently, the change in market volume is also relatively large (approximately 4.5 percent). These price and quantity impacts result in average deadweight losses of \$68,944 per year, and they aggregate to approximately \$2.07 million (\$1.23 million in present value) over the 30-year study period.

4.3. Total Cost of the Draft Proposed Rule

Table G.6 summarizes the cost of the draft proposed rule:

Table G.6: Total Cost of the Draft Proposed Rule

Costs of Draft 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
Total Costs	\$65.24	\$39.46

³⁷ The price impact is estimated with the formula $\Delta P = \Delta C_p \left(\frac{\varepsilon_s}{\varepsilon_s - \varepsilon_d} \right)$, which in this specific context means the change in price equals the change in long-term average cost (including a markup), times the ratio of the elasticity of supply to the difference between elasticity of supply and demand. Using the average change in production cost of \$10.67 plus a 38 markup for distribution, C_p equals \$14.73. The elasticity of supply and demand are estimated using the automobile vehicle market as a proxy (Goldberg, P) at 1.1 and -3.69, hence $\Delta P = \$14.73 \left(\frac{1.1}{1.1 - (-3.69)} \right) = \3.4 . This estimate differs slightly from the yearly estimates shown in the chart because the change in unit cost vary from year to year.

5. Benefits and Cost Analysis

Staff compared estimated benefits and costs to assess the relation between benefits and costs of the draft proposed rule. As noted, there is some degree of uncertainty in staff estimates of the number and cost of nonfatal injuries, due to previously discussed constraints in the NEISS data. Therefore, staff included only the benefits associated with reduced fatalities in this benefit-cost analysis.³⁸

Table G.7 below displays metrics for the benefits and costs of the draft proposed 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. These metrics show the draft proposed rule's benefits well exceed costs in each scenario.

Table G.7: Net Benefits of Draft Proposed 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 G.8 compares the benefits and costs on a per-unit basis, to add a marginal value perspective.³⁹ These metrics show the draft proposed rule's benefits well exceed costs at each scenario.

Table G.8: Per-APBR Net Benefits of Draft Proposed 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

³⁸ These societal costs (benefits in the model) from nonfatal injuries are normally estimated using the CPSC's NEISS data and the Injury Cost Model (ICM). However, due to ambiguity in the NEISS case descriptions, CPSC could not make definitive in-scope/out-of-scope determinations in almost all cases. Estimates of benefits and BCA ratios using estimates that include nonfatal injury should be viewed as an "upper bound" of the estimation.

³⁹ 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 proposed rule in the year in which they were 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.

5.1. Sensitivity Analysis

A major source of estimate uncertainty is the omission of injuries in the benefits assessment.⁴⁰ This may result in a significant under estimation of the benefits of the rule. In this sensitivity analysis, staff includes the benefits of averting all nonfatal injuries reported NEISS, despite the uncertainty of whether these incidents would be in-scope of this draft proposed rule. Staff presents these estimates as the theoretical upper bound of benefits from the draft proposed rule.

Staff used NEISS incidents and the Injury Cost Model (ICM) to extrapolate and generate national estimates for injuries from entrapment and strangulation treated in EDs and other settings. The ICM calculated that the aggregate number of nonfatal injuries in the United States from entrapment and strangulation from 2010 to 2019, was 125,121. Staff estimated that from the total of these injuries, 79,563 were treated in an outpatient setting (e.g., doctor's office, or clinic), 39,149 resulted in ED treatment, and 6,409 resulted in hospital admissions.

To forecast injuries from entrapment and strangulation into the future, staff used injury rates per million APBRs with its forecast of APBRs in use throughout the study period. Staff assumed injuries would stay the same as the average rates observed between 2010 to 2019: 1,293.6 hospital admissions per million APBRs in use; 7,902.2 emergency department admissions per million APBRs in use; and 16,059.7 doctor/clinic visits per million APBRs in use.

Staff forecasted APBRs in use using the population breakdown by age of APBR users, adjusted for population demographics and the growth of home healthcare spending. Figure G.12 below displays the estimated number of incidents for each death and injury category from 2010 through 2053, in the baseline scenario, which assumes the draft proposed rule does not go into effect.

⁴⁰ These societal costs (benefits in the model) are normally estimated using the CPSC's NEISS data and the ICM. However, due to ambiguity in the NEISS case descriptions, CPSC could not make definitive in-scope/out-of-scope determinations in almost all cases. Inclusion of nonfatal injury costs increases the benefit-cost ratio by approximately 200 percent.

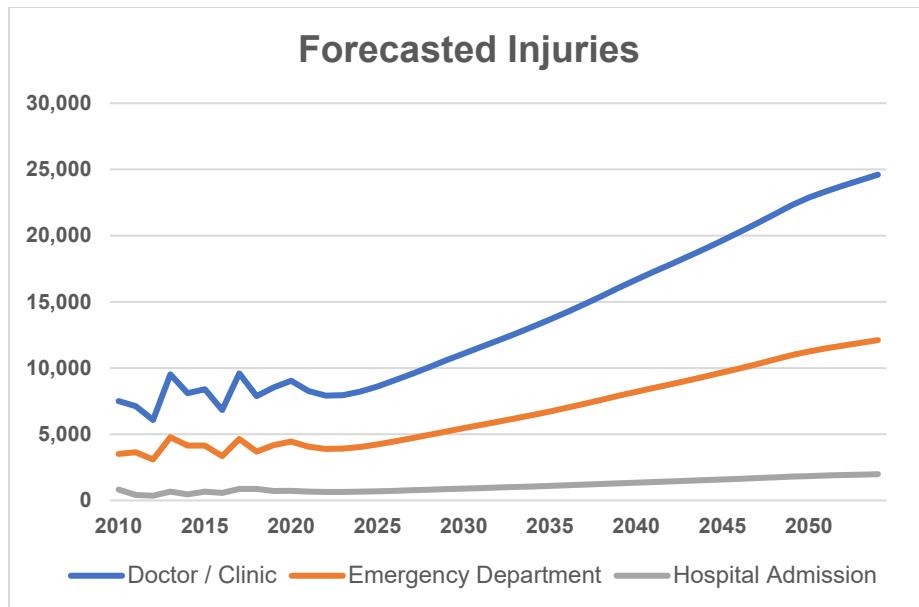


Figure G.12: Forecasted Injuries

Staff estimated the societal costs of nonfatal injuries using the ICM. The ICM is fully integrated with NEISS, and in addition to providing estimates of the societal costs of injuries reported through NEISS, the ICM also estimates the costs of medically treated injuries. The societal cost components provided by the ICM include medical costs, work losses, and the intangible costs associated with pain and suffering (Lawrence et al., 2018).

Medical costs include three categories of expenditures: (1) medical and hospital costs associated with treating the injured victim during the initial recovery period and in the long run, including the costs associated with corrective surgery, the treatment of chronic injuries, and rehabilitation services; (2) ancillary costs, such as costs for prescriptions, medical equipment, and ambulance transport; and (3) costs of health insurance claims processing. The ICM derives cost estimates for these expenditure categories from several national and state databases, including the Medical Expenditure Panel Survey (MEPS), the Nationwide Inpatient Sample of the Healthcare Cost and Utilization Project (HCUP-NIS), the Nationwide Emergency Department Sample (NEDS), the National Nursing Home Survey (NNHS), MarketScan® claims data, and a variety of other federal, state, and private databases.

Work loss estimates include: (1) the forgone earnings of the victim, including lost wage work and household work; (2) the forgone earnings of parents and visitors, including lost wage work and household work; (3) imputed long-term work losses of the victim that would be associated with permanent impairment; and (4) employer productivity losses, such as the costs incurred when employers spend time rearranging schedules or training replacement workers. The ICM bases these estimates on information from the MEPS, the Detailed Claim Information (a workers' compensation database) maintained by the National Council on Compensation Insurance, the National Health Interview Survey, the U.S. Bureau of Labor Statistics, and other sources.

The intangible costs of injury reflect the physical and emotional trauma of injury, as well as the mental anguish of victims and caregivers. Intangible costs are difficult to quantify because they do not represent products or resources traded in the marketplace. Nevertheless, they typically represent the largest

component of injury cost and need to be accounted for in any benefit-cost analysis involving health outcomes (Rice et al., 1989; Haddix, Teutsch, and Corso, 2003; Cohen and Miller, 2003; Neumann et al., 2016). The ICM develops a monetary estimate of these intangible costs from jury awards for pain and suffering. Although these awards can vary widely on a case-by-case basis, studies have shown these are systematically related to several factors, including economic losses, the type and severity of injury, and the age of the victim (Viscusi, 1988; Rodgers, 1993; Cohen and Miller, 2003). The ICM derives these estimates from a regression analysis of jury awards in nonfatal product liability cases involving consumer products compiled by Jury Verdicts Research, Inc.

The ICM estimates that the costs (in 2021 dollars) associated with nonfatal entrapment and strangulation injuries using the quality adjusted life years are: \$15,270 for injuries treated at the doctor's office/clinic; \$28,849 for injuries treated in the emergency department; and \$280,832 for injuries that result in hospital admission. Staff multiplied these estimates by the number of forecasted incidents from Figure B.4 to estimate societal cost from injuries through 2053. Figure G.13 shows the societal costs from casualties in the absence of the rule through 2053.

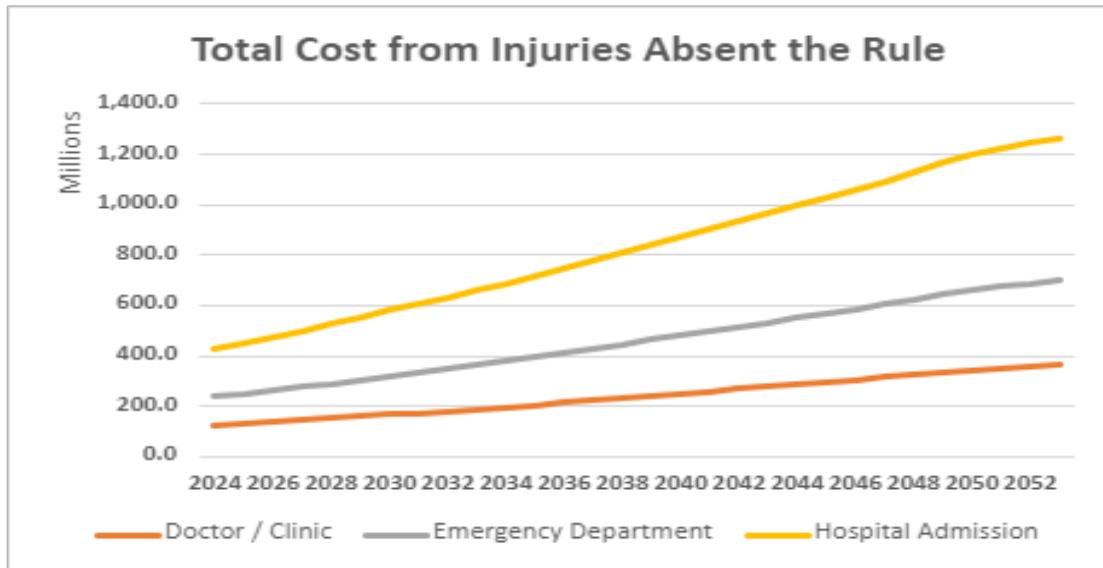


Figure G.13: Cost of Injuries

Over 30 years, staff estimates the societal costs from injuries associated with entrapments, annualized and discounted at 3 percent, to be \$195.52 million for doctor's office/clinic, \$179.49 million for ED, and \$289.64 million for hospital admissions.

Table G.9 below displays metrics for benefits, with nonfatal injuries included, and costs of the draft proposed rule.

Table G.9: Net Benefits of Draft Proposed Rule

Annualized Net Benefits (\$M, Discounted at 3%)	Portion of Benefits Achieved over the Baseline Efficacy Rate of Redesigned APBRs		
	75%	50%	25%
Benefits	\$698.73	\$465.82	\$232.91
Costs	\$2.01	\$2.01	\$2.01
Net Benefits (Benefits-Costs)	\$696.72	\$463.81	\$230.90
B/C Ratio	347.04	231.36	115.68

Table G.10 compares the benefits, with nonfatal injuries included, and costs on a per-unit basis.

Table G.10: Per-APBR Net Benefits of Draft Proposed Rule

Per-Unit Net Benefits (\$, Discounted at 3%)	Portion of Benefits Achieved over the Baseline Efficacy Rate of Redesigned APBRs		
	75%	50%	25%
Benefits	\$1,157.74	\$771.83	\$385.91
Costs	\$3.34	\$3.34	\$3.34
Net Benefits (Benefits-Costs)	\$1154.41	\$768.49	\$382.58
B/C Ratio	347.04	231.36	115.68

6. Staff Evaluation of the Voluntary Standard

To assess industry compliance with the voluntary standard, ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*, CPSC staff collected sample populations of APBR models and tested them, first in 2018 through 2019, and then again in 2021.^{41,42} In each instance, all APBRs examined by CPSC staff failed to comply with one or more substantive requirements of ASTM F3186 – 17. Staff discusses the results of this analysis in the Laboratory Sciences memo (Ota, 2022) (TAB D) and the Human Factors memo (Foster, 2022) (TAB C).

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 thought that their products currently conform; two indicated some modifications were required to bring their products into compliance; and two expressed uncertainties about 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. When asked if they believed most APBR

⁴¹ Sample populations were representative of the types of models offered for sale but not statistical samples of APBRs sold.

⁴² Models tested included those from firms which, in response to CPSC staff queries, indicated their products complied or partially complied with the voluntary standard.

manufacturers would conform to the voluntary standard, only one firm expressed the belief that at least 90 percent of the market would conform.

Based on CPSC testing and informal interviews, CPSC staff assessed there is no substantial industry compliance with the voluntary standard at this time. Furthermore, staff assesses substantial future industry compliance is unlikely because firms have had years to comply with the voluntary standard, and despite repeated outreach and testing, staff still has found no APBRs that comply with the standard.

7. Alternatives to the Draft Proposed Rule

Staff considered six alternatives to the draft proposed 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 proposed rule with a longer phased-in introduction. Staff does not recommend these alternatives for the following reasons:

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 grow with the use of APBRs over time, and the estimated \$298.11 million⁴³ 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.

7.2. Conduct Recalls Instead of Promulgating a Final Rule

The Commission could seek to recall APBRs in use that present a substantial product hazard. With this alternative, manufacturers could continue not complying with the voluntary standard and incurring no costs to modify or test APBRs to comply with the draft proposed rule. Furthermore, recalls only apply to an individual manufacturer and product, but do not extend to similar products; and recalls occur only after consumers have purchased and used such products and have been killed or injured due to exposure to the hazard. Additionally, recalls can only address products that are already on the market and cannot directly prevent unsafe products from entering the market. 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. For this reason, staff does not recommend this alternative.

7.3. Conduct Education Campaign on the Potential Risks Associated with APBR Use Instead of Promulgating the Draft Proposed Rule

The Commission could issue news releases or use other information and marketing techniques to warn consumers about entrapment and strangulation hazards associated with APBRs, instead of issuing a mandatory rule. Information and marketing campaigns, in conjunction with CPSC recall actions, may reduce the number of injuries and societal costs associated with APBR entrapment and strangulation hazards. However, marketing campaigns and recalls are not likely to be as effective at reducing the risk of injury from the entrapment and strangulation hazard as a mandatory standard. Furthermore, recalls

⁴³ 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.

occur only after consumers have been exposed to the hazard and potentially suffered injury or death due to the hazard. Therefore, staff does not recommend this alternative.

7.4. Total Ban of APBRs from the Market

The Commission could issue a total ban of APBRs. In making their recommendation regarding this alternative, staff weighed both quantifiable factors and unquantifiable factors of APBR use to the individual. Use of the APBR provides many unquantifiable benefits to users, including mobility, ease of access to beds, and the potential for at-home care. If the Commission promulgated 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 the product that provides utility to users, likely outweighs the benefits. Considering both the quantifiable and unquantifiable costs and benefits, staff determined that the net benefit of this alternative is likely less than that of the draft proposed rule. Therefore, staff does not recommend this alternative. Staff does, however, recommend soliciting comments on whether the proposed adoption of the modified ASTM standard sufficiently addresses the hazard and whether a ban is warranted, and if so, what the impact of a ban is on consumers (e.g., lost consumer utility from not having the product).

7.5. Require Enhanced Safety Warnings on APBRs Without Promulgating the Other Requirements in the Draft Proposed 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. Consequently, hazard communication through labeling, warnings, and instructions should be viewed as a "last resort" measure that supplements, rather than replaces, redesign or guarding efforts, unless these higher-level, hazard-control efforts are not feasible. Due to the likely continued use of APBRs at similar rates and fashions, 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 new rule with an introduction time greater than the 30 days recommended in this draft proposed rule. In making its recommendation regarding this alternative, staff weighed both quantifiable factors and unquantifiable factors of APBR use to the individual, and the producer. Due to the likely continued use of APBRs at similar rates until the rule's effective date, 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. Delaying the benefits of the rule likely results in higher social costs, in exchange for limited benefits to producers. Furthermore, manufacturers of APBRs have long had notice of the requirements of ASTM F3186 – 17, and so will be familiar with the core requirements of the proposed rule. For this reason, staff does not recommend this alternative.

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Tab H: Initial Regulatory Flexibility Analysis



Memorandum

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

DATE: September 14, 2022

THROUGH: Alex Moscoso, Associate Executive Director,
 Directorate for Economic Analysis

FROM: Rodney R. Row, Economist,
 Directorate for Economic Analysis

SUBJECT: Adult Portable Bed Rail Initial Regulatory Flexibility Analysis

Background

Whenever an agency publishes a notice of proposed rulemaking (NPR), Section 603 of the Regulatory Flexibility Act (RFA), 5 USC 601–612, requires agencies to prepare an initial regulatory flexibility analysis (IRFA), unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The IRFA, or a summary of it, must be published in the *Federal Register* with the proposed rule. Under Section 603(b) of the RFA, each IRFA must address:

- a description of why action by the agency is being considered;
- a succinct statement of the objectives of, and legal basis for, the proposed rule;
- a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed 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
- an identification to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule.

The IRFA must also describe any significant alternatives to the proposed rule that would accomplish the stated objectives and minimize any significant economic impact on small entities.

Discussion

A. Reason for Agency Action

The intent of this rulemaking 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. The Commission is considering this proposed rule because, although CPSC staff assesses compliance with the voluntary standard, ASTM F3186 – 17, *Standard*

Specification for Adult Portable Bed Rails and Related Products, would substantially reduce fatal and nonfatal injuries associated with APBR hazards, there is no evidence of substantial industry compliance.¹

B. Objectives and Legal Basis for the Rule

The Commission proposes this rule to reduce the risk of death and injury associated with APBRs. The Commission voted to grant Petition CP 13-1 and directed staff to draft an NPR on March 15, 2022. The rule is promulgated under the authority of the Consumer Product Safety Act (CPSA).

C. Small Entities to Which the Rule Will Apply

The proposed rule would apply to all manufacturers and importers of APBRs. 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). The U.S. Small Business Administration (SBA) size standards for NAICS classifications 339112, 339113, and 339999 are 1,000, 750, and 500 employees, respectively. EC staff identified seven U.S. APBR manufacturers that meet the SBA criteria for small businesses.

Importers of APBRs 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. Directorate for Economic Analysis (EC) staff identified one U.S. APBR firm in these categories that could be considered a small business.²

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

The proposed rule would establish a performance requirement for APBRs and test procedures that suppliers would have to meet to sell APBRs in the United States. The requirements and test procedures of the draft proposed standard are detailed in Howie, 2022 (Tab G). In summary, the draft proposed rule offers a performance requirement that APBRs must satisfy through the successful completion of testing and certification procedures. Specifically, APBRs sold in the United States must comply with ASTM F3186-17 standard, with the proposed modifications.

In 2019 and 2020, CPSC staff tested a sample of APBR models. None of the models met the performance requirements of the proposed rule. A second iteration 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 proposed rule, as well as costs related to testing and issuing a General Certificate of Conformity (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 proposed rule. According to Section 14 of the CPSA,

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.

² EC staff made these determinations using information from ReferenceUSAGov and Dun & Bradstreet.

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.

E. Federal Rules that May Duplicate, Overlap, or Conflict with the Proposed Rule

At the time of this document, no other federal rules duplicate, overlap, or conflict with the proposed rule.

F. Potential Impact on Small Entities

One purpose of the IRFA 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.” When CPSC staff cannot demonstrate that the impact is lower than 1 percent of gross revenue, staff prepares an IRFA.³

1. Impact on Small Manufacturers

The preliminary regulatory analysis (Tab H) discusses costs more fully. Based on that analysis, to achieve compliance with the proposed 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 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 this 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 unit sales in 2021. Staff found that the initial cost to comply with the proposed 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 proposed 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 proposed 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. It is unlikely that foreign manufacturers would exit a market growing at this rate, staff predicts. APBR importers also import other

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.

medical equipment, devices, and supplies. For these firms, any decline in APBR sales and revenue may be partially or fully offset by increasing sales and revenues of these 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 discussed in the regulatory analysis, staff estimated certification testing to be \$4,532 per model. This would not exceed 1 percent of the revenue for the one identified small importer, assuming this firm continues to import the same mix of products as in the pre-regulatory environment.

Conclusion

Staff identified seven manufacturers that meet the SBA criteria to be considered small firms. For three of these firms, the estimated cost from the proposed rule exceeds 1 percent of annual revenue. Staff assesses the proposed rule would have a significant economic impact on these three firms.

Staff has identified one importer of foreign manufactured APBRs that meets the SBA criteria to be considered small. A small importer whose supplier exits the market or does not provide the importer a GCC could experience a significant adverse economic impact. For this one small importer, the cost of certification testing would not exceed 1 percent of annual revenue. Furthermore, given the growing market, staff does not anticipate foreign manufacturers to exit the U.S. market, and staff assumes that foreign manufacturers would provide certifications on which small importers could rely, so that these foreign manufacturers could preserve their sales. Therefore, staff assesses the rule will not have a significant economic impact on APBR importers.

In summary, the proposed 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 the one small APBR importers.

The Commission welcomes public comments on this IRFA. Small businesses that believe they would be affected by the proposed rule are encouraged to submit comments. The comments should be specific and describe the potential impact, magnitude, and alternatives that could reduce the impact of the proposed rule on small businesses.

Appendix A:

2018-2019 APBR Market Compliance Mechanical Test Results

Table A1: 2018-2019 APBR Market Compliance ASTM F3186 – 17 Mechanical Test Results

Sample #	General Requirements			Performance Requirements					Label Permanency Requirements	Overall Result
	§5.1	§5.2	§5.3	§6.1	§6.2	§6.3	§6.4	§6.5	§9.1.2	
18-420-0003	M	M	NT	Not Met	M	Not Met	M	NT	M	Fail
18-420-0004	M	M	NT	Not Met	M	Not Met	M	NT	M	Fail
18-420-0005	M	M	NT	Not Met	M	Not Met	M	NT	Not Met	Fail
18-420-0006	M	M	NT	M	Not Met	Not Met	M	M	Not Met	Fail
18-420-0007	M	M	NT	Not Met	M	Not Met	M	M	Not Met	Fail
18-420-0008	M	M	NT	Not Met	M	Not Met	M	M	M	Fail
18-420-0009	M	M	NT	Not Met	M	Not Met	M	NT	M	Fail
18-420-0010	M	M	NT	M	Not Met	M	M	Not Met	Not Met	Fail
18-420-0011	M	M	NT	Not Met	Not Met	Not Met	M	NT	M	Fail
18-420-0012	M	Not Met	NT	Not Met	Not Met	Not Met	M	NT	Not Met	Fail
18-420-0013	M	M	NT	Not Met	Not Met	Not Met	M	NT	M	Fail
18-420-0014	M	M	NT	Not Met	Not Met	Not Met	M	M	Not Met	Fail
18-420-0015	M	M	NT	Not Met	Not Met	Not Met	M	M	Not Met	Fail
18-420-0016	M	M	NT	M	M	M	M	M	Not Met	Fail
18-420-0017	M	M	NT	Not Met	M	Not Met	M	Not Met	Not Met	Fail
18-420-0018	M	M	NT	Not Met	M	Not Met	M	NT	M	Fail
18-420-0019	M	M	NT	Not Met	M	Not Met	M	NT	NT	Fail
18-420-0020	M	M	NT	Not Met	M	Not Met	M	NT	Not Met	Fail

Table Key: M – The sample “Met” the requirement, NT – The sample was “Not Tested” to the requirement, Not Met – The sample did “not meet” the requirement, Fail – Sample “fails” to meet the requirements of ASTM F3186 – 17.

Table A2: 2018-2019 APBR Market Compliance ASTM F3186 – 17 Mechanical Test Results (Continued)

Sample #	General Requirements			Performance Requirements					Label Permanency Requirements	Overall Result
	§5.1	§5.2	§5.3	§6.1	§6.2	§6.3	§6.4	§6.5		
18-420-0021	M	M	NT	M	M	Not Met	M	NT	Not Met	Fail
18-420-0022	M	M	NT	Not Met	M	Not Met	M	NT	Not Met	Fail
18-420-0023	M	M	NT	Not Met	M	Not Met	M	Not Met	NT	Fail
18-420-0024	M	M	NT	Not Met	M	Not Met	M	NT	Not Met	Fail
18-420-0025	M	M	NT	Not Met	Not Met	Not Met	M	NT	Not Met	Fail
18-420-0026	M	M	NT	Not Met	Not Met	Not Met	NT	Not Met	Not Met	Fail
18-420-0027	M	M	NT	Not Met	M	Not Met	M	Not Met	Not Met	Fail
18-420-0028	M	M	NT	M	Not Met	Not Met	M	NT	NT	Fail
18-420-0029	M	M	NT	M	Not Met	Not Met	M	NT	NT	Fail
18-420-0030	M	M	NT	Not Met	Not Met	Not Met	M	NT	NT	Fail
18-420-0031	M	M	NT	Not Met	M	Not Met	M	NT	NT	Fail
18-420-0032	M	M	NT	Not Met	Not Met	Not Met	M	Not Met	Not Met	Fail
18-420-0033	M	M	NT	Not Met	Not Met	Not Met	NT	NT	NT	Fail
18-420-0034	M	M	NT	Not Met	Not Met	Not Met	NT	Not Met	NT	Fail
18-420-0035	M	M	NT	Not Met	M	Not Met	NT	NT	Not Met	Fail
18-420-0036	M	M	NT	M	M	Not Met	NT	Not Met	Not Met	Fail
18-420-0037	M	M	NT	Not Met	M	Not Met	M	NT	M	Fail

Table Key: M – The sample “Met” the requirement, NT – The sample was “Not Tested” to the requirement, Not Met – The sample did “not meet” the requirement, Fail – Sample “fails” to meet the requirements of ASTM F3186 – 17

Appendix B: 2021 APBR Market Compliance Test Results

Table B1: 2021 APBR Market Compliance ASTM F3186 – 17 Test Results

Sample #	General Requirements			Performance Requirements					Labeling, Warning, and Instructional Requirements			Overall Result
	§5.1	§5.2	§5.3	§6.1	§6.2	§6.3	§6.4	§6.5	§9.1	§9.2	§11	
21-420-0010	M	M	NT	Not Met	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0011	M	M	NT	Not Met	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0012	M	M	NT	Not Met	NT	NT	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0013	M	M	NT	M	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0014	M	M	NT	Not Met	Not Met	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0015	M	M	NT	Not Met	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0016	M	M	NT	Not Met	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0017	M	M	NT	Not Met	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0018	M	M	NT	M	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0020	M	M	NT	Not Met	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0021	M	M	NT	Not Met	Not Met	M	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0022	M	M	NT	Not Met	Not Met	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0023	M	M	NT	Not Met	Not Met	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0024	M	M	NT	Not Met	NT	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0025	M	M	NT	M	Not Met	M	NT	Not Met	Not Met	Not Met	Not Met	Fail
21-420-0026	M	M	NT	Not Met	Not Met	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail
21-420-0027	M	M	NT	M	Not Met	Not Met	NT	NT	Not Met	Not Met	Not Met	Fail

Table Key: M – The sample “Met” the requirement, NT – The sample was “Not Tested” to the requirement, Not Met – The sample did “not meet” the requirement, Fail – Sample “fails” to meet the requirements of ASTM F3186 – 17.