effective September 15, 2022, is amended as follows:

*Paragraph 5000 Class D Airspace.*

* * * * *

**ASO GA D Athens, GA [Amended]**

Athens/Ben Epps Airport, Athens, GA
(Lat. 33°56′55″ N, long. 83°19′33″ W)

That airspace extending upward from the surface to and including 3,300 feet MSL within a 4.6-mile radius of the Athens/Ben Epps Airport. This Class D airspace area is effective during the specified dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

*Paragraph 6002 Class E Surface Airspace.*

* * * * *

**ASO GA E2 Athens, GA [Amended]**

Athens/Ben Epps Airport, Athens, GA
(Lat. 33°56′55″ N, long. 83°19′33″ W)

That airspace extending upward from the surface within a 4.6-mile radius of the Athens/Ben Epps Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

*Paragraph 6004 Class E Airspace Designated as an Extension to Class D Surface Area.*

* * * * *

**ASO GA E4 Athens, GA [Amended]**

Athens/Ben Epps Airport, Athens, GA
(Lat. 33°56′55″ N, long. 83°19′33″ W)
(Athens Point of Origin)
(Lat. 33°56′51″ N, long 83°19′29″ W)

That airspace extending upward from the surface within 2.4 miles on each side of the Athens Point of Origin 195° bearing extending from the 4.6-mile radius of the Athens/Ben Epps Airport to 7.6 miles south of the Point of Origin, and within 1.4 miles each side of the Athens Point of Origin 076° bearing extending from the 4.6-mile radius of the airport to 7 miles east of the Point of Origin. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective date and time will thereafter be continuously published in the Chart Supplement.

*Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.*

* * * * *

**ASO GA E5 Athens, GA [Amended]**

Athens/Ben Epps Airport, GA
(Lat. 33°56′55″ N, long. 83°19′33″ W)

That airspace extending upward from 700 feet above the surface within a 7.7-mile radius of Athens/Ben Epps Airport.

Issued in College Park, Georgia, on November 2, 2022.

**Andreese C. Davis,**

*Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.*

[FR Doc. 2022–24348 Filed 11–8–22; 8:45 am]

**BILLING CODE 4910–13–P**

## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Part 1270

**[CPSC Docket No. CPSC–2013–0022]**

## Safety Standard for Adult Portable Bed Rails

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** 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 January 9, 2023.

*Deadline for Request to Present Oral Comments:* Any person interested in making an oral presentation must send an electronic mail (email) indicating this intent to the Office of the Secretary at *cpsc-os@cpsc.gov* by December 9, 2022.

**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 emailed 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 email, 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 email 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 CPSA to address an unreasonable risk of injury associated with APBRs. Gloria Black, the National Consumer

Voice for Quality Long-Term Care, Consumer Federation of America, and 60 other organizations 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, 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 March 9, 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 APBRs pose an unreasonable risk of injuries and deaths associated with entrapment hazards.[4] As discussed in section V. of this preamble, the Commission preliminarily determines that the voluntary standard is not likely to eliminate or adequately reduce the unreasonable risk of injury associated with entrapments on APBRs. Accordingly, the Commission is proposing to adopt the voluntary standard with specified modifications necessary to improve safety and adequately reduce the unreasonable risk of injury associated with entrapment on APBRs. 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)*

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

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

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

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

[4] The Commission voted 4–0 to approve this document.

[5] Available at: *https://www.cpsc.gov/s3fs-public/ProposedRuleSafetyStandardforAdultPortableBedRails.pdf?VersionId=Ypa89Iczh13C40Tq7EJRSMDZoatChf1.*

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 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.

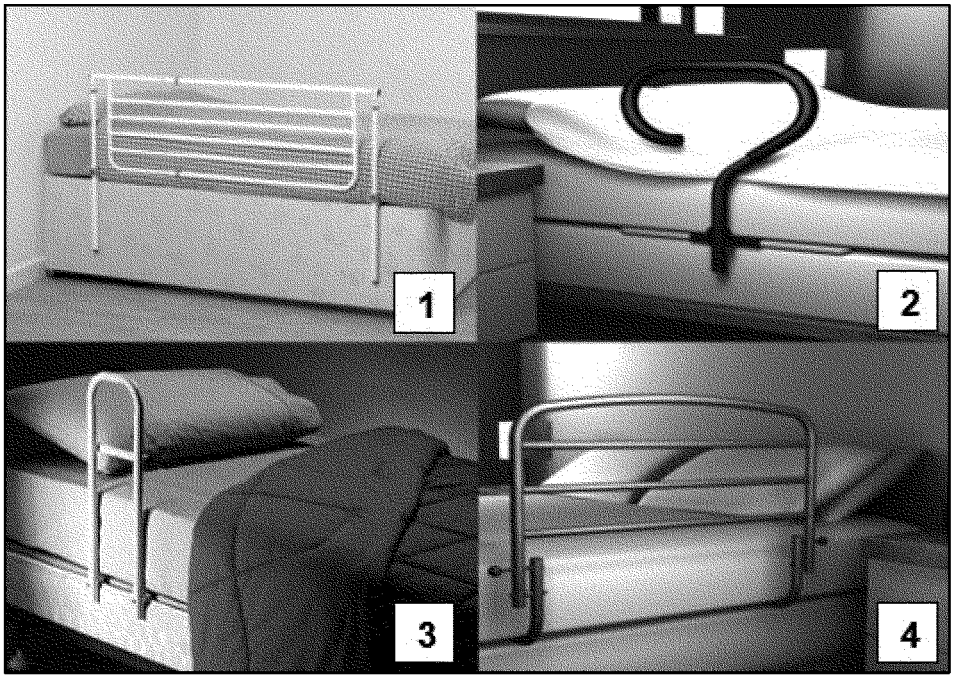



Figure 1: General examples of APBR types – (1) Full-Length Bed Rail, (2) Bed Cane, (3) Bed Handle, and (4) Half-Length Bed Rail

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

[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.

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.

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.

[7] All of these reported incidents occurred with APBRs that fall under the CPSC's jurisdiction.

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.

*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 briefing package) reviewed the incident

[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.*

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.

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 syndrome;[11] 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 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.

Based on staff's review of ASTM F3186–17, the Commission has preliminarily determined that the voluntary standard is not likely to eliminate or adequately reduce the unreasonable risk of injury associated with entrapments on APBRs. 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.

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

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

*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

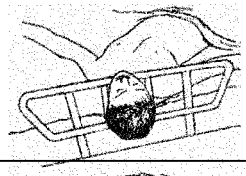
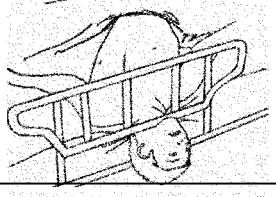
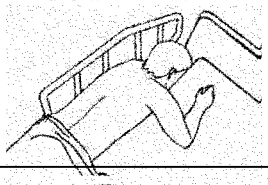
Staff identified entrapment as the most prevalent hazard pattern among the incidents. In accordance with the entrapment test methods specified in section 8 of the standard, section 6.3 of ASTM F3186–17 requires products to be tested to assess the potential for entrapment in four different zones. These 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

[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.

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 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**

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

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

TABLE 7—RAIL ENTRAPMENT INCIDENT LOCATIONS RELATIVE TO ASTM F3186–17 ENTRAPMENT ZONES

| Rail entrapment location | Entrapment testing location | Number 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.

For the reasons discussed in section V. of this preamble, the Commission preliminarily determines that the voluntary standard is not likely to eliminate or adequately reduce the unreasonable risk of injury associated with entrapments on APBRs. Accordingly, the Commission is proposing to adopt the voluntary standard with specified modifications necessary to improve safety and adequately reduce the unreasonable risk of injury associated with entrapment 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 8—ASTM F3186–17, 2018 APBR MARKET COMPLIANCE TESTING RESULT SUMMARY

| Section | Title | Number 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, 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 9—ASTM F3186–17, 2021 APBR MARKET COMPLIANCE TESTING RESULT SUMMARY

| Section | Title | Number of failed samples | Number 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

[13] The 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.

[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.*

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); and [16]
- 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.

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 § 1270.1—Scope, Application, and Effective Date*

Proposed § 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 § 1270.2—Requirements for Adult Portable Bed Rails*

Proposed § 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 § 1270(b):

1. Propose New Clarifying Definitions on ''Assembly'', ''Installation'' and ''Component''(Sections 3.18, 3.1.9, 3.1.10)

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

- Section 3.1.8: *Initial Assembly,* the first assembly of the product components after purchase, and prior to installing on the bed.
- Section 3.1.9: *Initial Installation,* the first installation of the product onto a bed or mattress.
- Section 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 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:

- Section 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.

- Section 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.''

[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.*

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

**⚠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.

Section 6.5.2: Revise ''Determining Misassembled Product: A product covered by this specification shall be considered misasssembled 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 ''misasssembled'' to ''misassembled.''

4. Propose New Sections to Address Mattress Variability (Section 6.2.1.1, Section 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:

• Section 6.2.1.1: If the manufacturer does not recommend a specific applicable range of mattress heights or thicknesses, the test personnel shall choose a mattress that provides the most severe condition per test requirement. If the product has adjustable settings, and the manufacturer does not recommend orienting or adjusting features on the product in a specific manner, the testers shall adjust the product to the most severe condition per test requirement.

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.

• Section 7.1.3: Mattress thickness ranges used for testing may be up to 1.5 in (38 mm) larger or smaller than the range specified by the manufacturer. If the manufacturer does not recommend a particular range of mattress heights, the testers shall choose a mattress that provides the most severe condition per test requirement. 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 sections 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 section 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 (Section 7.2) To Update References

• Section 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 (Sections 6.3.3, 8.4.5.4, and 6.4.1)

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

• Section 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 section 8.4.5, the horizontal centerline on the face of the 4.7 in (120 mm) end of the test probe (see 7.2) shall be above the highest point of the uncompressed mattress.''

• Section 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.''

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

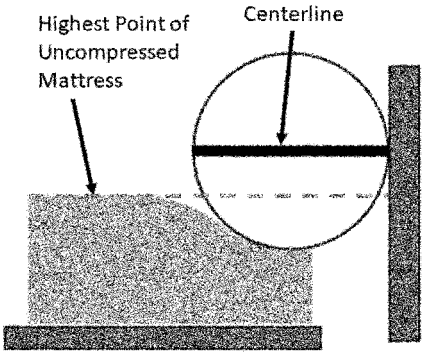



Figure 4a: Zone 3 **Pass** Criteria (Centerline **above** highest point of uncompressed mattress)

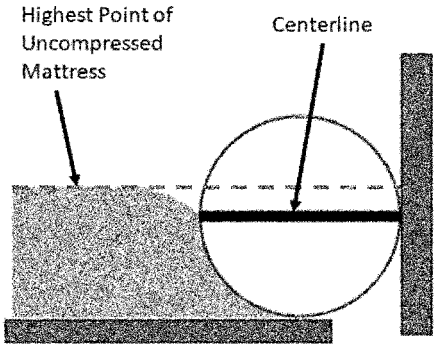



Figure 4b: Zone 3 **Fail** Criteria (Centerline **below** highest point of uncompressed mattress)

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.

• Section 6.4.1 Revise the measurements in ''Holes or slots that extend entirely through a wall section of any rigid material less than ¼ in (6.35 mm) thick and admit a ⅝ 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 ¼ in (6.35 mm) but are limited in depth to ¼ 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.

• Section 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.

• Section 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.

- Section 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.

- Section 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.

- Section 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 of ASTM F3186–17 currently requires that ''a 50 lbf force (222.5 N) force to be applied to the free end of the retention system in the horizontal direction,'' without adequately defining the term ''free end''. By adding a note to the end of section 8.6.3., 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:

- Section 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.

- Section 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.

- Section 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.

- Section 11.1.1.3: Revise ''In addition to contacting the manufacturer directly, consumers should report

problems to the CPSC at is 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. Description of Proposed § 1270.3—Prohibited Stockpiling*

The CPSC is proposing an anti-stockpiling provision to prevent firms from manufacturing large quantities of non-compliant APBRs before the rule takes effect and seeks comment on this provision. This section would make it a prohibited act for manufacturers and importers to manufacture or import APBRs that do not comply with the requirements of this part in any 1-month period between the date of publication of the final rule and the effective date of the final rule at a rate that is greater than 105 percent of the rate at which they manufactured or imported APBRs during the base period for the manufacturer or importer. The proposed base period for APBRs would be the calendar month with the median manufacturing or import volume within the last 13 months immediately preceding the month of promulgation of a final rule.

*D. Proposed Findings—§ 1270.4*

The findings required by section 9 of the CPSA are discussed throughout this preamble and set forth in § 1270.4 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 the annualized present value of the potential societal costs of the proposed rule is $298.11 million. If 92 percent of deaths caused by entrapment are addressed by the proposed rule, there are potential annual benefits of $266.99 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 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 proposed 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 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 costs 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 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:

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 |

[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.

[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—Continued

| Costs of proposed rule | Total cost ($M) | Present value ($M) |
|---|---|---|
| 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

| 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 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) | 1,154.41 | 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 voluntary standard is not likely to eliminate or adequately reduce the unreasonable risk of injury associated with entrapments on APBRs. Further, 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 U.S.C. 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 proposed 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 distributers. 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 end of the comment period, 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; email: *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 (E.O.) 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 × 6 models per entity × 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 × 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 × 6 models per entity × 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 × 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 December 9, 2022, to the Office of Information and Regulatory Affairs, OMB as described under the **ADDRESSES** section of this document.

## 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 proposing an anti-stockpiling provision to prevent firms from manufacturing large quantities of non-compliant APBRs before the rule takes effect and seeks comment on this provision.

## 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);
- Any qualitative or quantitative evidence concerning the utility that APBRs have for consumers relative to alternative products that might be used as substitutes in the event APBRs are banned; and
- The appropriateness of the 30-day effective date, and a quantification of how a 30-day effective date would affect the benefits and costs of the proposed rule.

## 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 document.

## 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 in 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 part 1270 to read as follows:

## PART 1270—SAFETY STANDARD FOR ADULT PORTABLE BED RAILS

Sec.



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

### § 1270.1 Scope, application, and effective date.

This part 1270 establishes a consumer product safety standard for adult portable bed rails manufactured after [DATE 30 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

### § 1270.2 Requirements for adult portable bed rails.

(a) Except as provided in paragraph (b) of this section, each adult portable bed rail must comply with all applicable provisions of ASTM F3186–17, *Standard Specification for Adult Portable Bed Rails and Related Products,* approved on August 1, 2017. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A read-only copy of the standard is available for viewing on the ASTM website at *https://www.astm.org/READINGLIBRARY/.* You may obtain a copy from ASTM International, 100 Barr Harbor Drive, P.O. 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, email *cpsc-os@cpsc.gov,* or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *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) Under section 6.1.3, permanently attached retention system components shall not be able to be removed without the use of a tool after initial assembly.

(ii) [Reserved]

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

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

(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 section 8.4.5, the horizontal centerline on the face of the 4.7 in (120 mm) end of the test probe (see 7.2) shall be above the highest point of the uncompressed mattress.

(ii) [Reserved]

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

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

(ii) [Reserved]

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

(i) Under section 6.5.1, any structural components and retention system components of a product covered by this specification that require consumer assembly or adjustment, or components that may be removed by the consumer without the use of a tool, shall not be able to be misassembled when evaluated to 6.5.2.

(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 sections 6.1–6.4.

(ii) [Reserved]

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

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

a mattress that provides the most severe condition per test requirement.

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

(ii) [Reserved]

(9) 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:

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

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

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

(ii) [Reserved]

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

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

(ii) [Reserved]

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

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

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

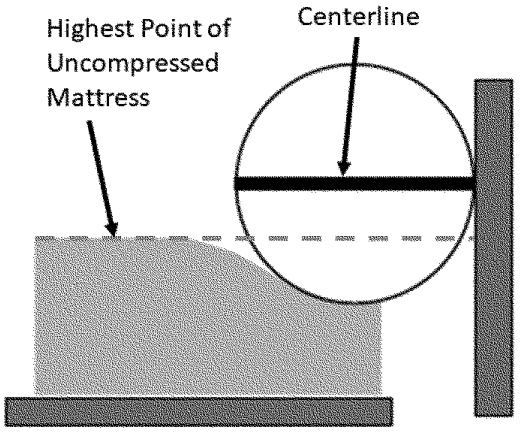
(14) Instead of complying with section 8.4.5.4 of ASTM F3186–17, comply with the following:

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

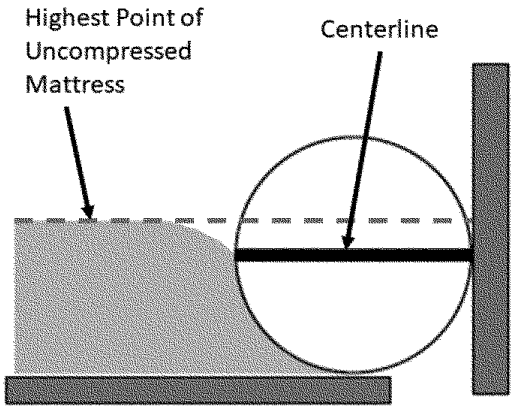
(A) If the line on the face of the 4.7 in (120 mm) end of the cone is above the highest point of the uncompressed mattress, as shown in Figure 1 to paragraph (b)(14) of this section, the space passes the test.

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

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




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




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

(ii) [Reserved]

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

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

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

(i) Under section 9.1.1.3, that the product is to be used only with the type and size of mattress and bed, including the range of thickness of mattresses, specified by the manufacturer of the product. If beds with head or footboards

are allowed, the distance between the head or footboard and the placement of the product shall be indicated to be >12.5 in (318 mm).

(ii) [Reserved]

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

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

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

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

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

**⚠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) Under section 11.1.1.3, in addition to contacting the manufacturer directly, consumers should report problems to the CPSC at its website *SaferProducts.gov* or call 1–800–638–2772, or to the FDA at 1–800–332–1088.

(ii) [Reserved]

### § 1270.3 Prohibited stockpiling.

(a) *Prohibited acts.* Manufacturers and importers of adult portable bed rails (APBRs) shall not manufacture or import APBRs that do not comply with the requirements of this part in any 1-month period between [DATE OF PUBLICATION OF FINAL RULE] and [EFFECTIVE DATE OF FINAL RULE] at a rate that is greater than 105 percent of the rate at which they manufactured or imported APBRs during the base period for the manufacturer or importer.

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

### § 1270.4 Findings.

(a) *General.* The Consumer Product Safety Act (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 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:

(i) Take no regulatory action;

(ii) Conduct a recall of APBRs instead of promulgating a final rule;

(iii) Conduct an educational campaign;

(iv) Require enhanced safety warnings; and

(v) Longer effective date.

(3) 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 the voluntary standard is not likely to eliminate or adequately reduce the unreasonable risk of injury associated with entrapments on APBRs. Accordingly, the Commission is proposing to adopt the voluntary standard with specified modifications necessary to improve safety and adequately reduce the unreasonable risk of injury associated with entrapment on 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:

(i) Within the product;

(ii) Between rail support(s) and the bed mattress, when applicable, under the product;

(iii) Between the product and the mattress; and

(iv) Between the underside of the end of the product and the mattress.

(2) 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.

(3) 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.

(4) 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 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 societal costs 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 and produce estimated benefits of $266.99 million. 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:

(i) Take no regulatory action;

(ii) Conduct a recall of APBRs instead of promulgating a final rule;

(iii) Conduct an educational campaign;

(iv) Ban APBRs from the market entirely;

(v) Require enhanced safety warnings; and

(vi) Longer effective date.

(4) 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.*

[FR Doc. 2022–22692 Filed 11–8–22; 8:45 am]

**BILLING CODE 6355–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 300

**[REG–100719–21]**

**RIN 1545–BQ26**

## User Fees Relating to Enrolled Actuaries; Correction

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Correction to a notice of proposed rulemaking and notice of public hearing.

**SUMMARY:** This document contains a correction to a notice of proposed rulemaking and notice of public hearing (REG–100719–21) published in the **Federal Register** on October 5, 2022. The notice of proposed rulemaking contains proposed amendments to the regulations relating to user fees for enrolled actuaries.

**DATES:** Written or electronic comments are being accepted and must be received by December 19, 2022. Requests to speak and outlines of topics to be discussed at the public hearing scheduled for January 9, 2023, at 10:00 a.m. EST must be received by December 19, 2022.

**ADDRESSES:** Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–100719–21) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish any comment to the public docket for public availability. Send paper submissions to: CC:PA:LPD:PR (REG–100719–21), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

**FOR FURTHER INFORMATION CONTACT:** Concerning the proposed regulation, Carolyn M. Lee at (202) 317–6845; concerning cost methodology, Michael A. Weber at (202) 808–9738; and concerning submission of comments, the hearing, and the access code to attend the hearing by telephone, Regina Johnson, 202–317–6901 (not toll-free numbers) or *publichearings@irs.gov.*

**SUPPLEMENTARY INFORMATION:**

### Background

The proposed regulations and notice of public hearing subject to this correction are under section 9701 of Title 31 of the United States Code.

### Correction of Publication

Accordingly, the notice of proposed rulemaking and notice of public hearing (REG–100719–21) that is the subject of FR Doc. 2022–21458, published on October 5, 2022 (87 FR 60357), is corrected to read as follows:

1. On page 60358, in the first column, under the caption **DATES**, the paragraph is corrected to read, ''Electronic or written comments must be received by December 19, 2022. The public hearing will be held by teleconference on January 9, 2023, at 10:00 a.m. EST. Requests to speak and outlines of topics to be discussed at the public hearing must be received by December 19, 2022. The public hearing will be canceled if no outlines are received by December 19, 2022. Requests to attend the public hearing must be received by 5:00 p.m. EST on January 5, 2023. The telephonic hearing will be made accessible to people with disabilities. Requests for