The unique features of the side stick must therefore be demonstrated through flight and simulator tests to have suitable handling and control characteristics when considering the following:

1. The handling-qualities tasks and requirements of the Airbus Model A321neo XLR airplane special conditions, and other 14 CFR part 25 requirements for stability, control, and maneuverability, including the effects of turbulence.

2. *General ergonomics:* Armrest comfort and support, local freedom of movement, displacement angle suitability, and axis harmony.

3. Inadvertent input in turbulence.

4. Inadvertent pitch-roll crosstalk.

The FAA Handling Qualities Rating Method (HQRM) of Appendix E of the *Flight Test Guide for Certification of Transport Category Airplanes,* AC 25–7D, may be, but is not required to be, used to show compliance.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions apply to Airbus Model A321neo XLR airplanes. Should Airbus apply later for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model series of airplanes. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Airbus Model A321neo XLR airplanes.

(a) *Pilot Strength.* In lieu of the ''strength of pilots'' limits of § 25.143(d) for pitch and roll, and in lieu of the specific pitch force requirements of §§ 25.145(b) and 25.175(d), the following applies:

The applicant must show that the temporary and maximum prolonged force levels for the side-stick controllers are suitable for all expected operating conditions and configurations, whether normal or non-normal.

(b) *Controller Coupling.* The electronic side-stick controller coupling design must provide for corrective and/or overriding control inputs by either pilot with no unsafe characteristics. Annunciation of controller status must be provided and must not be confusing to the flightcrew.

(c) *Pilot Control.* The applicant must show by flight tests that the use of side-stick controllers does not produce unsuitable pilot-in-the-loop control characteristics when considering precision path control tasks and turbulence. In addition, pitch and roll control-force sensitivity and displacement sensitivity must be compatible, so that normal inputs on one control axis will not cause significant unintentional inputs on the other.

Issued in Kansas City, Missouri, on July 17, 2023.

Patrick R. Mullen,

Manager, Technical Policy Branch, Policy and Standards Division, Aircraft Certification Service.

[FR Doc. 2023–15466 Filed 7–20–23; 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: Final rule.

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

DATES: The rule is effective on August 21, 2023. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of August 21, 2023.

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

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

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

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

On April 23, 2014, staff sent a briefing package on APBRs to the Commission

(Staff's 2014 briefing package).[1] In that briefing package, staff recommended the Commission defer a decision on the petition until a voluntary standard for APBRs was developed and evaluated by staff. On April 29, 2014, the Commission voted to defer the petition pending ASTM's further work on a voluntary standard.

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

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

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

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

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

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

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

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

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

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

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

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

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

II. The Subject Products

Several types of bed rails under CPSC jurisdiction are available to consumers.[7]

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

[5] On July 5, 2023, the Commission voted 4–0 to approve this document. Chair Hoehn-Saric and Commissioner Trumka issued statements in connection with their votes available at: *https://www.cpsc.gov/About-CPSC/Chairman/Alexander-Hoehn-Saric/Statement/Statement-of-Chair-Alexander-Hoehn-Saric-on-Issuance-of-a-Final-Safety-Standard-for-Adult-Portable-Bed-Rails* and *https://www.cpsc.gov/About-CPSC/Commissioner/Richard-Trumka/Statement/CPSC-Finalizes-Rock-Solid-New-Safety-Rule-for-Adult-Bedrails-Saving-Lives-and-300M-a-Year-in-Costs-to-Americans.*

[6] Available at: *https://www.cpsc.gov/s3fs-public/Final-Rule-Safety-Standard-for-Adult-Portable-Bed-Rails.pdf?VersionId=CUfr4q0N1VaGv2o8jnGyQziiWcg8qfu3.*

[7] Information on adult bed rails regulated by the U.S. Food and Drug Administration (FDA) is

Continued

ASTM F3186–17 (section 1.2) describes ''portable bed rails and related products'' as products installed by consumers and ''not designed as part of the bed by the bed manufacturer.''

Generally, APBRs within CPSC's jurisdiction include products that are installed or used alongside a bed by consumers and are intended to reduce the risk of falling from the bed, assist the consumer in repositioning in the bed, or assist the consumer in transitioning into or out of the bed. Figure 1 below shows four common types of APBRs.

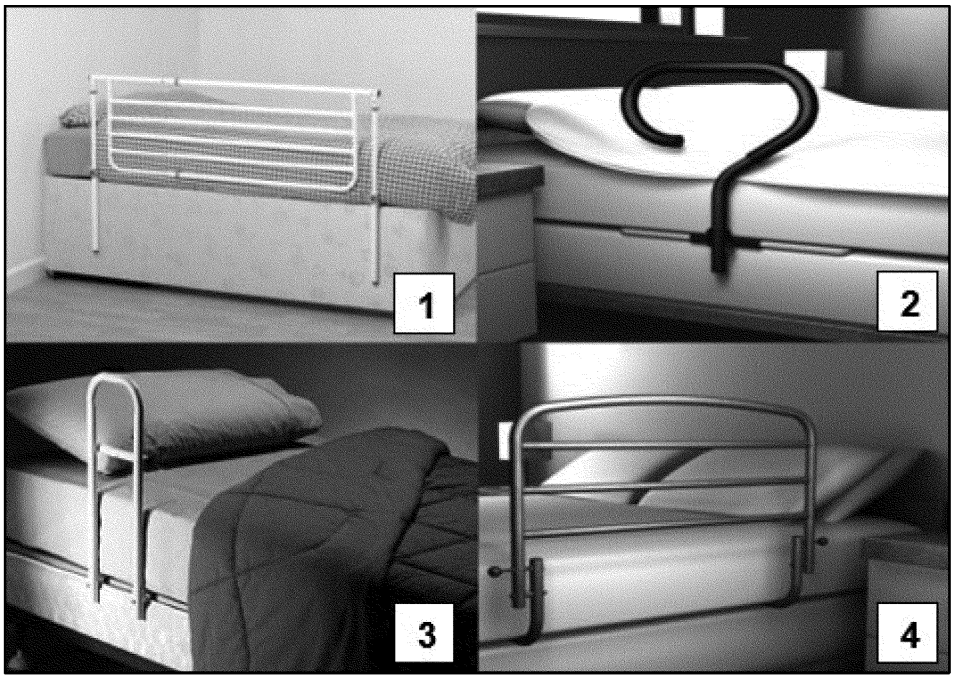


Figure 1: General examples of APBR types – (1) Full-Length Bed Rail, (2) Bed Cane, (3) Bed Handle, and (4) Half-Length Bed Rail

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

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

III. Risk of Injury

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

A. CPSRMS Reports

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

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

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

Table 1 below presents the distribution of these APBR incidents by age.

TABLE 1—DISTRIBUTION OF REPORTED APBR-RELATED INCIDENTS BY AGE

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

Source: CPSRMS (2003–2021).

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

TABLE 2—DISTRIBUTION OF REPORTED APBR-RELATED INCIDENTS BY GENDER

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

Source: CPSRMS (2003–2021).

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

TABLE 3—DISTRIBUTION OF REPORTED APBR-RELATED INCIDENTS BY LOCATION

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

Source: CPSRMS (2003–2021).
* Includes care home/center, foster home, group home, retirement center, adult family home and hospice.

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

TABLE 4—DISTRIBUTION OF REPORTED APBR-RELATED INCIDENTS BY MEDICAL CONDITION

Condition	Fatalities	Nonfatalities	Total
Cardiovascular disease	87	0	87
Alzheimer's/Dementia/Mental	73	0	73
Mobility/Paralysis/Stroke	20	0	20
Parkinson's disease	17	1	18
Pulmonary disease	11	0	11

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

TABLE 4—DISTRIBUTION OF REPORTED APBR-RELATED INCIDENTS BY MEDICAL CONDITION—Continued

Condition	Fatalities	Nonfatalities	Total
Cancer	7	0	7
Cerebral palsy	6	0	6
Multiple sclerosis	5	0	5
*Other**	21	0	21
Unknown/Not Reported	123	21	144

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

B. NEISS Reports

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

TABLE 5—NEISS ESTIMATES FOR INJURIES RELATED TO ADULT BED RAILS, JANUARY 2003–DECEMBER 2021

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

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

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

C. Hazard Patterns

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

- More than 75 percent of the victims were age 70 or older.
- More than 80 percent of the reported fatalities involved victims ages 70 or older.
- Fifty-eight percent of victims suffered from at least one underlying medical condition.
- Almost 34 percent of victims were reported to have more than one medical condition.

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

- *Rail Entrapment:* There were 284 fatalities and two not-fatal injuries related to rail entrapment. This category includes incidents in which the victim was caught, stuck, wedged, or trapped between the mattress/bed and the bed rail, between bed rail bars, between a commode and rail, between the floor and rail, between the night table and rail, or between a dresser and rail. Based on the narratives, the most frequently injured body parts were the neck and head.
- *Falls:* There were 23 deaths, one nonfatal knee fracture, and one non-

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

injury incident related to falls. This category includes incidents in which the victim fell off the bed, fell and hit the bed rail, or hit and fell near the bed rail, and fell after climbing over the bed rail.

- *Structural Integrity:* There were 11 incidents related to structural component problems (weld of bed rail broke and bed rail not sturdy). This category includes one laceration, one head bump, one bruise, two unspecified injuries, and six non-injury incidents.
- *Miscellaneous:* There were 10 incidents with miscellaneous problems (hanging on the bed rail after garment got caught, hand, arm, or leg laceration, pinched radial nerve against the bed rail, complaint about a misleading label, complaint about a bed rail that was noncompliant with the ASTM standard, and a claim against a bed rail manufacturer about an unspecified issue). This category includes three deaths, three lacerations, one pinched nerve, one unspecified injury, and two non-injury incidents.

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

The vast majority of nonfatal incident reports (all reports except one) did not list any underlying medical condition. Of the 310 fatal incidents, approximately 34 percent reported the victim to have multiple medical conditions, and approximately 58 percent of incidents reported at least one underlying medical condition. Preexisting chronic medical conditions or disorders included Alzheimer's disease, dementia, and other mental limitations; Parkinson's disease; cerebral palsy; multiple sclerosis; Lesch-Nyhan syndrome; amyotrophic lateral sclerosis; cancer; cardiovascular disease; and pulmonary disease. Other conditions included victims with stroke, paralysis, seizures, heavy sedation, and drug ingestion. These factors can limit mobility or mental acuity and contribute to the risk of death by entrapment, because individuals with these conditions are particularly vulnerable and often cannot respond to the danger and free themselves. As discussed in Tab B of the staff's NPR briefing package, adult aging issues can contribute to entrapments, including age-related declines in muscular strength, muscular power, motor control and coordination, and balance. Consumers 70 years and older, who are the victims in most APBR-related fatalities, are especially vulnerable to such age-related declines.

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

IV. ASTM F3186–17

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

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

Staff's review of ASTM F3186–17 shows that the voluntary standard, with modifications, is likely to eliminate or adequately reduce the entrapment hazards associated with ABPRs. The Commission determines, however, that the voluntary standard is not likely to eliminate or adequately reduce the risk of entrapments on ABPRs without modifications. In addition, based on testing of ABPRs conducted by CPSC staff as discussed below, the Commission determines that substantial compliance with the voluntary standard is unlikely. Accordingly, in the final rule the Commission incorporates by reference ASTM F3186–17, with modifications, to address the entrapment hazards associated with APBRs.

A. Assessment of ASTM F3186–17 Performance Requirements

1. Terminology

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

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

ASTM F3186–17 (section 3.1.2) defines ''adjacent type bed rail'' as:

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

The Commission determines that these definitions are appropriate for addressing hazards associated with APBRs that: (1) are installed or used along the side of a bed and intended to reduce the risk of falling from the bed; (2) assist the consumer in repositioning in the bed; or (3) assist the consumer in transitioning into or out of the bed.

2. General Requirements

Section 5 of ASTM F3186–17 sets out general requirements. Section 5.1 requires that there will be no hazardous sharp points or edges. Section 5.2 states that any exposed parts shall be smooth and free from rough edges. Section 5.3 requires that products covered by the standard that are installed on an adjustable bed that articulates must meet the performance requirements when the bed is in either the flat or articulated position. General requirements mandating smooth edges on exposed parts improve safety by preventing potential lacerations or skin

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

injuries from APBRs. In addition, testing APBR products on articulating beds allows assessment of openings that could potentially lead to entrapment after the bed is adjusted from the flat position to the articulated position.

3. Performance Requirements

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

a. Misassembly and Misinstallation

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

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

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

b. Falls

Falls were the second most common hazard pattern in the incident data, accounting for 25 incidents (8 percent). If the fall was triggered by the APBR becoming dislodged, or if its position shifted, then these incidents potentially may be addressed by the voluntary standard's structural integrity testing and the requirement of a permanently attached retention system to maintain the installed product in position. However, some fall-related incidents involved the victim deliberately climbing over the APBR and this requirement may not prevent such consumers from falling over the bed rail.

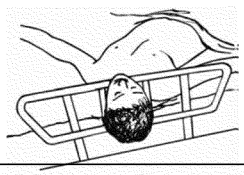
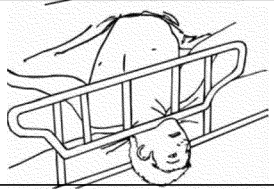
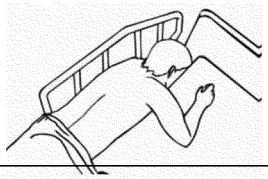
c. Entrapment Testing

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

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

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

Table 6: ASTM F3186 – 17 Entrapment Zones

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

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

TABLE 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	Zone 2, 3, or 4	200
Within APBR itself	Zone 1	8
Against outside of APBR	None	5
Between APBR and headboard	None (Zone 6)	1
Unknown location	Unknown	70
Total		284

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

d. Labeling, Warning, and Instructional Literature Requirements

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

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

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

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

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

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

B. Assessment of Compliance to ASTM F3186–17

Staff conducted two rounds of market compliance testing to ASTM F3186–17: the first round in 2018 and 2019, the second round in 2021. In both rounds, no APBRs met all requirements of ASTM F3186–17. All products failed at least one critical mechanical requirement, such as retention strap performance, structural integrity, and entrapment. As described in Tabs C and D of the staff's NPR briefing package and the staff's final rule briefing package, an APBR that fails any one mechanical performance requirement could result in a fatal entrapment. Furthermore, all products failed the labeling, warning, and instructional requirements. This section discusses market compliance with ASTM F3186–17.

1. 2018–2019 Market Compliance Testing

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

TABLE 8—ASTM F3186–17, 2018 APBR MARKET COMPLIANCE TESTING RESULT SUMMARY

Section	Title	Number of failed samples	Failure rate (percent)
(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.

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

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

All 35 models failed the labeling, warning, and instructional literature requirements. None of the 35 models

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

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

2. 2021 Market Compliance Testing

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

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

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

TABLE 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 Literatue:			
11	Instructional Literature	17	17

3. CPSA Section 15 Compliance Actions 2021–2022

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

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

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

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

4. Market Compliance Testing Summary

The Commission determines that, without additional modifications as discussed in the NPR and below, the voluntary standard is insufficient to eliminate or adequately reduce the unreasonable risk of injury of entrapments presented by APBRs. Moreover, based on staff's test results showing that there is no market compliance with the voluntary

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

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

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

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

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

standard, the Commission determines that substantial compliance to a voluntary adult portable bed rail safety standard is unlikely. Accordingly, the Commission rule incorporates by reference, ASTM F3186–17 with modifications, to require ABPR manufacturers to comply with the fundamental requirements of the mandatory standard and thereby improve safety.

V. Response to Comments

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

A. Banning APBRs

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

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

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

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

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

Comment: Gloria Black, NCHR, Consumer Voice, Public Citizen, and CANHR identified several alternatives to using APBRs, such as: bed trapezes, adjustable beds, non-slip mattress pads, bed exit alarms, body pillows, and medical attendees.[18] Gloria Black specifically identified ''no cost options'' including lowering the bed or placing the mattress on the floor to prevent falls, placing cushioning on the floor to prevent serious injury, and placing a sturdy nightstand or table next to the bed to assist individuals in getting in and out of bed. Additionally, CANHR stated that APBRs are ''used primarily as physical restraints for the convenience of others, and almost always unnecessary and in nursing homes'' and per ''the Nursing Home Reform Law of 1987's prohibition of physical restraints for the convenience of staff, safe alternatives to prevent injury from falls have been practiced for decades in compliant facilities.''

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

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

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

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

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

The Commission disagrees with the commenter's assertion that an undue impact will occur to long term care facilities. In the NPR's Preliminary Regulatory Analysis, CPSC staff considered the effect of the proposed rule on APBR price, the dead weight loss (the lost consumer and producer surplus resulting from price-induced decrease in APBR sales) associated with the price change, cost, and net benefits. Staff estimated the proposed rule would increase manufacturer costs in the first year by approximately $5.40 per APBR,

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

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

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

D. Hole Size Requirements

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

Response: As reported in Tab A of the staff briefing package for the NPR, about 7,400 of the estimated 79,500 adult bed rail-related injuries treated in emergency departments from 2003 to 2021 were hand or finger injuries. Of these, about 3,400 were identified as injuries to fingers, most of which involved crushing or laceration.[21]

Section 6.4 of ASTM F3186–17 addresses the risk of finger entrapment and laceration in small holes or openings. Changes to this section are necessary to correct errors and inconsistent measurement references. Specifically, in stating the dimensions of the rods used to conduct testing, the standard inaccurately refers to 13 mm as the equivalent to 5⁄8 in. (whereas 5⁄8 in. is approximately 16 mm). Also, while the standard allows different dimensions for holes or slots that do not exceed 1⁄4 in. in depth, it refers to a drawing depicting a hole up to ''.375 (9.53 mm) deep,'' or 3⁄8 in., shown below in Figure 2.

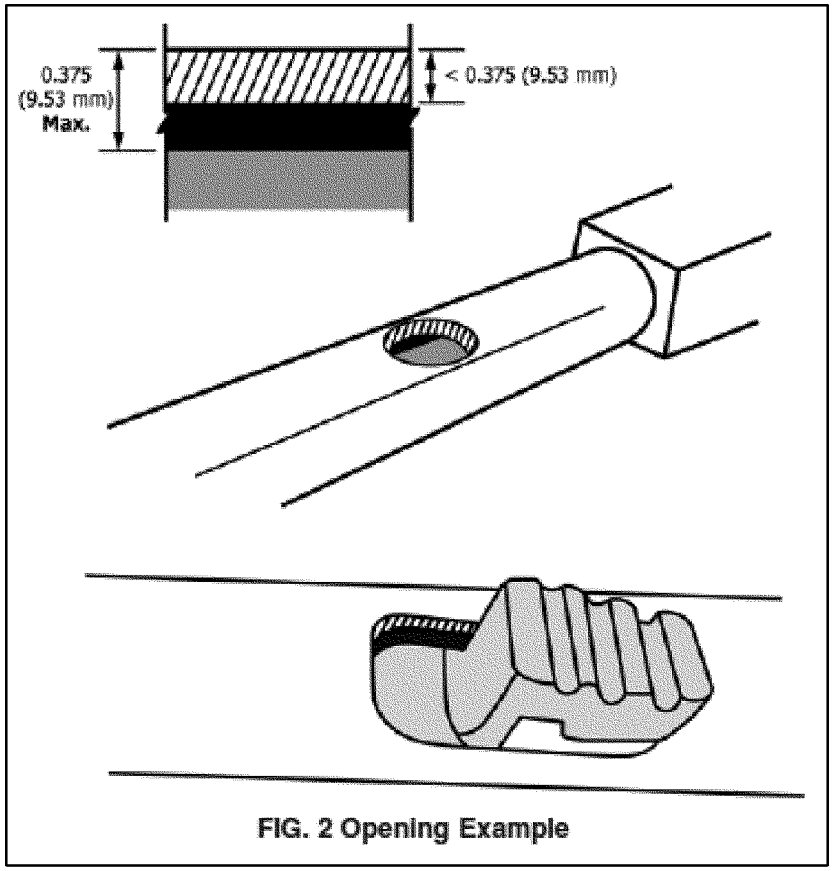


Figure 2: Illustration from Figure 2 of ASTM F3186 – 17, Section 6.4

Further, the proposed changes in the NPR are necessary to adequately address the risk of injury because the hole dimensions referenced by the commenter are not effective in protecting vulnerable adult populations. Vulnerable adults are often smaller and more frail than other populations of adults and are more likely to use APBR

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

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

products. The proposed changes in the NPR align the rule with other established children's product regulations that prevent hazards to a range of finger sizes that covers both children and adult users simultaneously.[22]

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

E. Proposed Entrapment Test Modifications

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

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

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

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

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

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

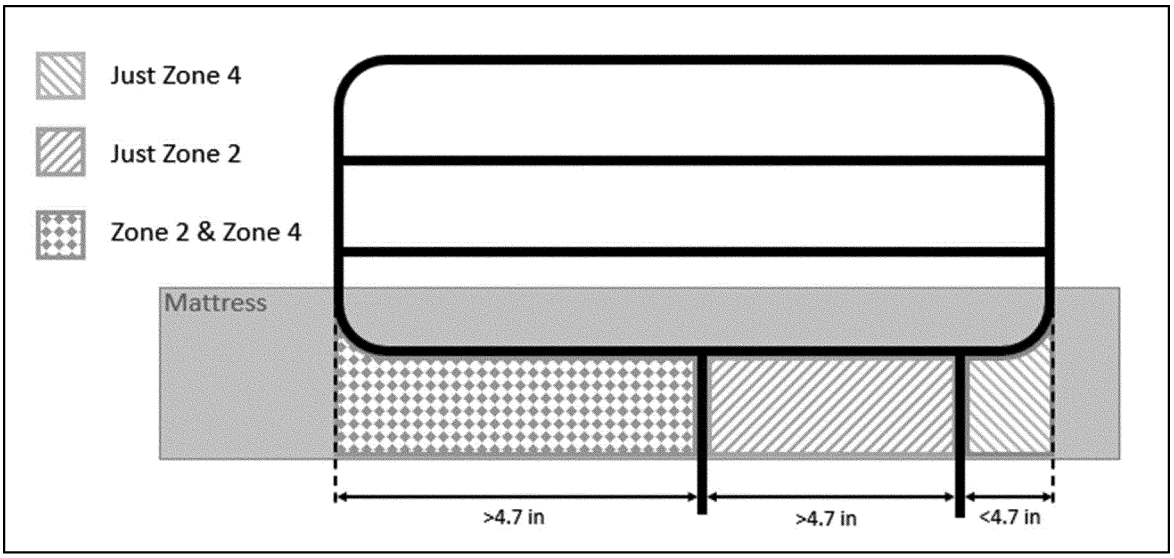


Figure 3: General example of areas subject to Zone 2 requirements.

Safety testing should represent known hazard modes, including the displacement caused by consumers moving or pushing into the mattress or product, which may create an opening that was not previously visible. During entrapment zone testing, the positioning and application of the force via a force gauge must be realistic and representative of all reasonably foreseeable scenarios of consumer behavior. In many cases, applying the force to the probe by attaching a force gauge below the bottom of the rail is the most accurate representation of the worst case of this foreseeable hazard scenario. Additionally, in contrast to the current voluntary standard, entrapment hazards are not present only in the ''largest opening'' of a product. Entrapment hazards may exist in several

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

areas depending on the product configuration and installation.

To ensure entrapment hazards are adequately addressed, products must be assessed in all areas that may constitute an entrapment zone. Therefore, in response to this comment, the Commission has revised the language in the final rule as follows:

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

F. Removing Mattress Thickness Selection for Testers

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

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

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

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

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

G. Language Modifications for Mattress Thickness Selection

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

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

H. Banning Retention Straps

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

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

I. Modifying the Proposed Definition of ''Conspicuous''

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

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

J. Adding ''Conspicuous'' to Warning Labeling Requirements

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

Response: The warning in section 9.2.7 of ASTM F3186 is directly related to product installation. As discussed in the NPR briefing package, the warning should draw attention to the installation component and encourage its use during installation (16 CFR part 1224, the children's bed rail standard, has this same warning requiring it to be on an ''installation'' component). Therefore, it is unnecessary for the warning on the product to be conspicuous in the manufacturer's recommended use position. Additionally, ASTM F3186–17 requires separate warnings that address

entrapment hazards and securing the APBR to the bed that are required to be placed on a conspicuous component of the product and/or packaging/instructions. Therefore, the warning in section 9.2.7 should be on an installation component but is not required to be conspicuous for the reasons discussed above.

K. Making Compliance Testing Records Publicly Available

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

Response: Manufacturers and importers of APBRs will be required to issue a General Certificate of Conformity (GCC) under section 14 of the CPSA and 16 CFR part 1110 for the APBR mandatory standard. A GCC requires manufacturers or importers to certify that their general use products comply with all applicable consumer product safety rules (or similar rules, bans, standards, or regulations) under any law enforced by the Commission for that product. A GCC must accompany the applicable product or shipment of products covered by the certificate. A manufacturer or importer must furnish the GCC to distributors or retailers. Based on the available information there is not significant evidence indicating that the commenter's proposed requirement that manufacturers also provide records of compliance testing directly to consumers will substantially decrease the known hazards related to APBRs given the existing GCC framework.

L. Reorganizing Labeling Requirements

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

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

M. Adding Labeling Requirements for Intended Use

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

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

N. Adding Email Address to Contact Information Requirements

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

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

O. Adding Language to Warning Statements

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

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

P. Adding Drawings in Instructional Literature Requirements

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

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

Q. Stockpiling

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

R. Effective Date

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

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

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

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

Finally, for clarity, we disagree with Stander's claim that ''the CPSC has

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

VI. Description of the Final Rule

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

A. Section 1270.1—Scope, Application, and Effective Date

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

B. Section 1270.2—Requirements for Adult Portable Bed Rails

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

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

1. Section 1270.2(b)(1)

A comment from APBR seller Stander indicated that the proposed rule is ambiguous regarding the testing of entrapment zones. ASTM F3186–17 does not define the term ''entrapment zone.'' The preamble of the NPR referenced both the FDA guidance document and incident data to explain how the entrapment zones will be identified, and the different ways entrapment can occur within the entrapment zones. However, adding a global definition for ''entrapment zone'' to the final rule will clarify what areas must be tested. Therefore, § 1270.2(b)(1)(i) of the final rule includes a new definition for ''entrapment zone,'' which is defined as ''An area, gap, or opening that can potentially capture or restrain a person's body part. Hazardous openings may not always be visible prior to testing.'' The three original definitions in proposed § 1270.2(b)(1) have been renumbered from proposed § 1270.2(b)(1)(i) through (iii) to § 1270.2(b)(1)(ii) through (iv) in the final rule to account for the addition of the new definition of entrapment zone in § 1270.2(b)(1)(i) of the final rule.

2. Section 1270.2(b)(3)

Based on Stander's comment that recommended revisions to the proposed language for mattress thickness selection, the Commission is removing from § 1270.2(b)(3)(i) of the final rule language that could be interpreted as exempting manufacturers from including a range of compatible mattress thicknesses, which is contradictory to the intent of the standard.

3. Section 1270.2(b)(8)

A comment from Consumer Voice was submitted indicating that the original proposed language seems to create an alternative requirement for manufacturers that do not provide a recommended thickness range, as required by section 9.1.1.3 of the voluntary standard. Based on the comment, § 1270.2(b)(8)(i) of the final rule adds an additional range that will increase safety by accounting for foreseeable differences between nominal and actual mattress thicknesses, as well as consumer mattress selection that deviates from manufacturer recommendations.

4. Section 1270.2(b)(9)

Proposed § 1270.2(b)(9) contained the introductory instruction of ''In addition to complying with section 7.2 of ASTM F3186–17'', when it should have read ''Instead of complying with section 7.2 of ASTM F3186–17''. The final rule has been revised to correct this error.

5. Section 1270.2(b)(11) and (13)

Based on a comment from Stander, the language in proposed § 1270.2(b)(11)(i) and (b)(13)(i) has been revised in the final rule to remove restrictions on how the probe and force should be applied, and thereby better represent the known hazard patterns and ensure consistent interpretations of the test methods. Applying the force perpendicular to the 2.4-inch end of the probe may not always emulate the potential hazard of head or limb entrapment. Therefore, the language in § 1270.2(b)(11)(i) and (b)(13)(i) of the final rule has been revised to ''in the direction most likely to lead to failure of the requirement'' to make it clearer and more easily understood by safety testing personnel.

6. Section 1270.2(b)(12)

Also based on a comment from Stander, § 1270.2(b)(12)(i) has been revised in the final rule to remove restrictions on how the probe and force should be applied to better represent the known hazard patterns. The language in § 1270.2(b)(12)(i) of the final rule has been revised to read ''at the angle most likely to allow it to pass through'' to make it clearer and more easily understood by safety testing personnel.

7. Section 1270.2(b)(14) (previously proposed § 1270.2(b)(13)(ii))

The requirements of proposed § 1270.2(b)(13)(ii) in the NPR have been renumbered as revised § 1270.2(b)(14) in the final rule. Therefore, proposed § 1270.2(b)(14) through (19) have been renumbered as § 1270.2(b)(15) through (20) in the final rule. Revised § 1270.2(b)(14) has been modified from the proposed rule because proposed § 1270.2(b)(13) introductory text incorrectly stated that the language ''Instead of complying with [the applicable ASTM provision]'' applied to both § 1270.2(b)(13)(i) and (ii). The introductory instructional text for proposed § 1270.2(b)(13)(ii) should have read ''In addition to complying with [the applicable ASTM provision]''. Therefore, in the final rule, § 1270.2(b)(14) has been revised to provide the correct introductory text.

Additionally, § 1270.2(b)(14)(i) in the final rule has been revised from proposed § 1270.2(b)(13)(ii). Stander raised concerns about the location of Zone 2 on bed rails with multiple supports. Zone 2 testing is meant to address head-first entry under the rail into any opening between the mattress compressed by the weight of a consumer's head and a section of the bedrail. Bed rails that have overhanging

elements longer than 4.7 inches can allow the passage of the head in a manner consistent with identified Zone 2 entrapment hazards regardless of the number or location of vertical support rails. 4.7 inches is the diameter of the test probe and encompasses the 5th percentile female head breadth. Therefore, revised § 1270.2(b)(14)(i) clarifies which areas should be included in Zone 2 testing along with adding a new figure 1 illustration that visually depicts the clarifying language.

C. Section 1270.3—Prohibited Stockpiling

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

D. Findings in Appendix A to the Part

The findings required by section 9 of the CPSA are discussed throughout the preamble of this rule and set forth in appendix A to part 1270. While the findings have updated for the final rule, they are substantively the same as the proposed findings in the NPR.

VII. Final Regulatory Analysis

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

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

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

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

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

1. Benefits of the Final Rule

The expected benefits and costs of the final rule are discussed below. The most common hazard pattern among all reported incidents is rail entrapment, accounting for more than 90 percent (284 of 310) of the fatal incidents. CPSC uses the period 2010 through 2019 for its rates of fatalities because, at the time of the NPR, it was the most recent 10-year window where all or nearly all incidents have been reported. The NPR identified 158 deaths from entrapment that occurred from 2010 through 2019. This number accounts for 92 percent of observed death incidents; the remaining 8 percent were caused by underlying incidents that may or may not be prevented by the final rule. To forecast entrapment deaths into the future, CPSC used death rates per million APBRs in conjunction with its forecast of APBRs in use throughout the study period. The NPR assumed deaths would stay the same as the average rates observed between 2010 to 2019: 31.9 deaths per million APBRs.

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

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

The Commission has not included non-fatal injuries in the foregoing benefit-cost assessment because for many incidents involving such injuries, there is not sufficient information to determine whether they would be prevented by the final rule. However, non-fatal injuries have been quantified and monetized in a sensitivity analysis as a potential upper limit to assess the benefits of this final rule. Further, the requirements of the final rule are expected to address the 92 percent of deaths caused by entrapment. However, because we do not assume the final rule will eliminate all deaths caused by entrapment, we assessed potential benefits for the final rule under three scenarios, estimating benefits at 75 percent, 50 percent, and 25 percent of the 92 percent baseline efficacy.

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

TABLE 10—BENEFITS OF THE FINAL RULE

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

2. Costs of the Final Rule

The Commission's regulatory assessment of the costs of the final rule assumes that 100 percent of manufacturers will fully redesign their APBR models to comply with ASTM F3186–17, with the final rule's modifications. Like the benefits estimation, the time span of the cost analysis covers a 30-year period that starts in 2024, which is the expected year of implementation of the final rule. This cost analysis presents all cost estimates in 2021 dollars. This cost analysis also discounts costs in the future and uses a 3 percent discount rate to estimate their present value.

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

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

TABLE 11—TOTAL COST OF THE FINAL RULE

Costs of proposed rule	Total cost ($M)	Present value ($M)
Cost of Redesigning Existing Models	$2.75	$2.59
Cost of Production of Redesigned APBRs	60.43	35.65
Deadweight Loss	2.07	1.23

3. Net Benefits of the Final Rule

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

TABLE 12—ANNUALIZED NET BENEFITS OF FINAL RULE

Annualized net benefits ($M, discounted at 3%)	Portion of benefits achieved over the baseline efficacy rate of redesigned APBRs		
	75%	50%	25%
Benefits	$200.24	$133.49	$66.75
Costs	$2.01	$2.01	$2.01
Net Benefits (Benefits − Costs)	$198.23	$131.48	$64.73
B/C Ratio	99.45	66.30	33.15

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

TABLE 13—PER-APBR NET BENEFITS OF THE FINAL RULE

Per unit net benefits ($, discounted at 3%)	Portion of benefits achieved over the baseline efficacy rate of redesigned APBRs		
	75%	50%	25%
Benefits	$331.78	$221.19	$110.59
Costs	$3.34	$3.34	$3.34
Net Benefits (Benefits − Costs)	$328.45	$217.85	$107.26
B/C Ratio	99.45	66.30	33.15

B. Voluntary Standard

Based on staff's evaluation of ASTM F3186–17, the Commission determines that ASTM F3186–17, with appropriate modifications, will address the entrapment hazard presented by APBRs. As discussed in the preamble of the NPR, and Tabs C and D of both the staff's NPR briefing package and the staff's final rule briefing package, CPSC staff collected sample populations of APBR models and tested them, first in 2018 through 2019, and then again in 2021. In each instance, all APBRs examined by staff failed to comply with one or more substantive requirements of ASTM F3186–17.

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

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

C. Alternatives to the Final Rule

The Commission considered six alternatives to the final rule adopted here: (1) take no regulatory action; (2) continue to conduct recalls of APBRs instead of promulgating a rule; (3) conduct an educational campaign instead of promulgating a rule; (4) ban APBRs from the market; (5) require enhanced safety warnings without other requirements; and (6) implement the rule with a later effective date. The Commission finds that none of these alternatives would adequately address the hazards associated with APBRs.

1. No Regulatory Action

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

2. Conduct Recalls Instead of Promulgating a Final Rule

The Commission could seek voluntary or mandatory recalls of APBRs that present a substantial product hazard. With this alternative, manufacturers could continue producing noncompliant products without incurring any additional costs to modify or test APBRs for compliance with the final rule. Furthermore, recalls only apply to an individual manufacturer and product, but do not extend to similar hazardous products. Recalls also occur only after consumers have purchased and used such products with possible resulting deaths or injuries due to exposure to the hazard. Additionally, recalls can only address products that are already on the market but do not directly prevent unsafe products from entering the market. Recalls have removed several APBR models from the U.S market since 2021. However, despite these efforts, APBR sales volume remains at, or near, the 2020 pre-recall level and non-compliant APBRs remain widely available for purchase, which is to be expected given the APBR market's low barriers to entry. Therefore, a significant portion of the estimated $298.11 million average annualized societal costs would likely continue to be incurred by consumers in the form of deaths and injuries. Further, even if recalls had reduced the size of the APBR market or the share of the market comprised of non-compliant APBRs, staff assesses the rule's benefits still would exceed the rule's costs. The final rule provides significant benefits that far exceed costs even if the draft final rule is only 75%, 50%, or 25% effective. Therefore, the Commission does not find this alternative would address the unreasonable risk of injury associated with APBRs.

3. Conduct Education Campaigns

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

the unreasonable risk of injury associated with APBRs.

4. Ban APBRs From the Market

The Commission could ban APBRs under CPSA section 8. Staff weighed quantifiable and unquantifiable factors concerning the utility of APBR use in making a recommendation regarding this alternative. The use of APBRs provides many unquantifiable benefits to users, including mobility, ease of access to beds, protection against falls, and the potential for at-home care. If the Commission promulgated a rule banning APBRs, the benefits from reduced deaths and injuries would be similar to this final rule, or potentially even greater. However, the value of individual users' lost utility could outweigh the incremental benefits of this approach. Considering both the quantifiable and unquantifiable costs and benefits, staff assessed that the net benefits of this alternative are likely less than those of the final rule. In addition, under CPSA section 8, the Commission may only declare a product to be a banned hazardous product if no feasible consumer product safety standard would adequately protect the public from the unreasonable risk of injury associated with APBRs. 15 U.S.C. 2057. The Commission finds that this final rule would adequately protect the public from this risk. Therefore, the Commission does not adopt the alternative of a ban on APBRs.

5. Enhanced Safety Warnings on APBRs

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

6. Later Effective Date

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

VIII. Final Regulatory Flexibility Analysis

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

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

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

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

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

(5) a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and

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

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

A. Need For and Objective of the Final Rule

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

B. Significant Issues Raised by Comments

Seven comments were submitted in response to the NPR. Some of the comments described possible economic impacts of the rule, including economic impacts on firms, the utility of the product for consumers, costs associated with the product hazards, and alternative actions that the Commission could take. However, none of the comments specifically addressed, or resulted in changes to, the initial regulatory flexibility analysis. A summary of the significant issues with possible economic impacts and a summary of staff's assessment of such issues is contained in section V of the preamble and in the Appendix to Tab C of the staff's briefing package for the final rule. The Chief Counsel for Advocacy of the Small Business Administration did not file a comment on the NPR.

C. Small Entities to Which the Rule Will Apply

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

D. Compliance, Reporting, and Recordkeeping Requirements of Final Rule

The final rule establishes a performance requirement for APBRs and test procedures that suppliers would

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

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

E. Impact on Small Entities

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

F. Other Significant Alternatives to the Rule Considered

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

IX. Incorporation by Reference

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

In accordance with the OFR regulations, section IV. of this preamble summarizes the major provisions of ASTM F3186–17 that the Commission incorporates by reference into 16 CFR part 1270. The standard itself is reasonably available to interested parties. Until the final rule takes effect, a read-only copy of ASTM F3186–17 is available for viewing, at no cost, on ASTM's website at: *https://www.astm.org/CPSC.htm.* Once the rule takes effect, a read-only copy of the standard will be available for viewing, at no cost, on the ASTM website at: *https://www.astm.org/READINGLIBRARY/.* Interested parties can also schedule an appointment to inspect a copy of the standard at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, telephone: (301) 504–7479; 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.*

X. Paperwork Reduction Act

This rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3521). The preamble to the NPR discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of CPSC's estimates. 87 FR 67586 (Nov. 9, 2022). The NPR described the provisions of the proposed rule and provided an estimate of the annual reporting burden for the rule under the PRA. *See* 87 FR 67605. The estimated burden of this collection of information is unchanged from the NPR. CPSC did not receive any comments regarding the information collection burden in the NPR through OMB. OMB has assigned control number 3041–0192 to this information collection.

XI. Effective Date

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

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

XII. Certification

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

XIII. Preemption

Executive Order 12988, Civil Justice Reform (Feb. 5, 1996), directs agencies to specify the preemptive effect of a

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

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

XIV. Environmental Considerations

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

XIV. Congressional Review Act

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

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

XV. Findings

As explained, the CPSA requires the Commission to make certain findings when issuing a consumer product safety standard. 15 U.S.C. 2058(f)(1), (f)(3). These findings are stated in appendix A to part 1270 and are based on information provided throughout this preamble and the staff's briefing packages for the proposed and final rules.

List of Subjects in 16 CFR Part 1270

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

■ For the reasons discussed in the preamble, the Commission amends 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 establishes a consumer product safety standard for adult portable bed rails manufactured after August 21, 2023.

§ 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. This incorporation by reference (IBR) material is available for inspection at the U.S. Consumer Product Safety Commission and at the National Archives and Records Administration (NARA). Contact the U.S. Consumer Product Safety Commission at: 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.* 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.* 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.*

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

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

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

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

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

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

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

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

(ii) [Reserved]

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

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

(ii) [Reserved]

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

(i) *Zone 3.* When tested in accordance with section 8.4.5 of ASTM F3186–17, the horizontal centerline on the face of the 4.7 in (120 mm) end of the test probe (see paragraph (b)(9)(i) of this section) shall be above the highest point of the uncompressed mattress.

(ii) [Reserved]

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

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

(ii) [Reserved]

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

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

(ii) [Reserved]

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

(i) *Determining misassembled product.* A product covered by this specification shall be considered misassembled if it appears to be functional under any condition and it does not meet the requirements of sections 6.1 through 6.4 of ASTM F3186–17.

(ii) [Reserved]

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

(i) Mattress thickness ranges used for testing shall be up to 1.5 in. (38 mm) larger or smaller than the range specified by the manufacturer. Test personnel shall choose a mattress and product setting configuration that provide the most severe condition for each test requirement in the standard.

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

(ii) [Reserved]

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

(i) *Entrapment test probe.* The test probe used for the entrapment tests shall be as described in the Food and Drug Administration (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) Substitute the following text as the content of Note 1 in section 8.4 of ASTM F3186–17:

(i) The tests described in this section are similar to those described in the referenced FDA Guidance Document.

(ii) [Reserved]

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

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

(ii) [Reserved]

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

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

(ii) [Reserved]

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

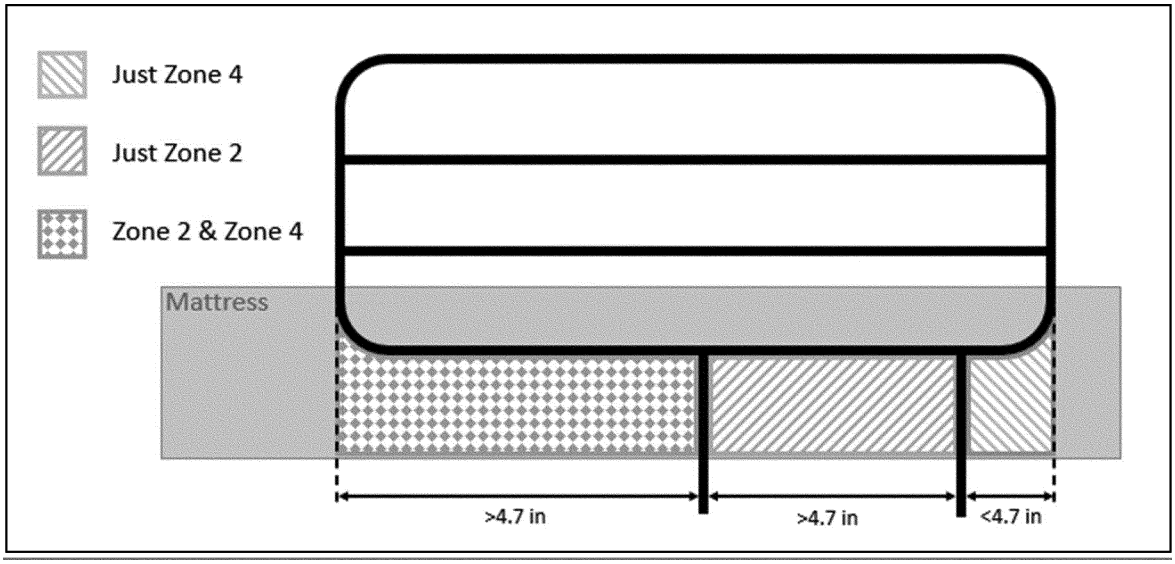
(i) If the test probe does not pull through freely use the force gauge to exert a 22.5 lbf (100 N) pulling force to the 2.4 in (60 mm) cylindrical end of the cone in the direction most likely to lead to failure of the requirement.

(ii) [Reserved]

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

(i) If a horizontal section of the rail greater than 4.7 in exists along the bottom of the rail, that section must also meet the Zone 2 requirements regardless of the number or location of the supports. Repeat testing described in section 8.4.4.3 of ASTM F3186–17 (see paragraph (b)(12)(i) of this section) and section 8.4.4.4 of ASTM F3186–17 (see paragraph (b)(13)(i) of this section) for all applicable entrapment zones. Figure 1 to this paragraph (b)(14)(i) shows a general example of areas subject to Zone 2 requirements.

Figure 1 to paragraph (b)(14)(i)—General Example of Areas Subject to Zone 2 Requirements



(ii) [Reserved]

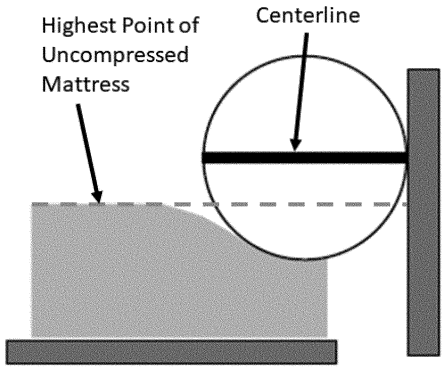
(15) Instead of complying with section 8.4.5.4 of ASTM F3186–17, comply with the following:

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

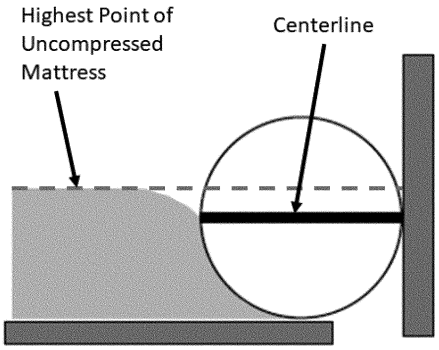
(A) If the line on the face of the 4.7 in (120 mm) end of the cone is above the highest point of the uncompressed mattress, as shown in Figure 2 to this paragraph (b)(15)(i), the space passes the test.

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

Figure 2 to paragraph (b)(15)(i)—Zone 3 Test: (a) Pass, (b) Fail



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



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

(ii) [Reserved]

(16) In addition to complying with section 8.6.3 of ASTM F3186–17, use the following definition:

(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.

(ii) [Reserved]

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

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

(ii) [Reserved]

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

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

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

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

(ii) [Reserved]

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

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

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

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

(ii) [Reserved]

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

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

(ii) [Reserved]

§ 1270.3 Prohibited stockpiling.

(a) *Prohibited acts.* Manufacturers and importers of adult portable bed rails (APBRs) shall not manufacture or import APBRs that do not comply with the requirements of this part between July 21, 2023, and August 21, 2023, 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 July 21, 2023.

Appendix A to Part 1270—Findings Under the Consumer Product Safety Act

The Consumer Product Safety Act requires that the Commission, in order to issue a standard, make the following findings and include them in the rule. 15 U.S.C. 2058(f)(3). Because of this, the facts and determinations in these findings apply as of the date the rule was issued, July 21, 2023.

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

B. 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.

C. Need of the Public for the Products and Probable Effect on Utility, Cost, and Availability of the Product.

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

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

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

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

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

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

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

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

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

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

H. Reasonable Relationship of Benefits to Costs. (1) The benefits expected from the rule bear a reasonable relationship to its cost. The rule reduces the entrapment hazard and other hazards associated with APBRs, and thereby reduces the societal costs of the resulting injuries and deaths. The rule is expected to address the 92 percent of deaths caused by entrapment, resulting in potential societal benefits of $298.11 million. Benefits additionally were assessed under three scenarios derived from this expected efficacy, estimating benefits at: 75 percent, 50 percent, and 25 percent of their potential value. Under these three scenarios, the estimated quantifiable annualized benefits of the rule are approximately $200.24 million, $133.49 million, and $66.75 million, respectively. The costs associated with the rule's requirements to prevent the hazards associated with APBRs are expected to be approximately $2.01 million per year. On a per product basis, the estimated benefits of the rule are approximately $331.78, $221.19, and $110.59 per APBR when assessed at 75 percent, 50 percent, and 25 percent of their potential value, respectively, and the costs are approximately $3.34 per APBR. All these amounts are in 2021 dollars using a discount rate of 3 percent.

(2) The requirements of the rule, with modifications, are expected to address 92 percent of deaths caused by entrapment. Even under the most conservative assumption that only 25 percent of the potential benefits are achieved, every $1 in costs for the market to adopt the rule equates to approximately $33.15 in benefits to society. The estimated annualized net benefits of the rule are approximately $198.23 million, $131.48 million, and $64.74 million, at when benefits are assessed at 75 percent, 50 percent, and 25 percent of their potential value, respectively.

I. Least-Burdensome Requirement that Would Adequately Reduce the Risk of Injury. The Commission considered six alternatives to the rule including: take no regulatory action; continue to conduct recalls of APBRs instead of promulgating a rule; conduct an educational campaign without a rule; ban APBRs from the market entirely; require enhanced safety warnings without other requirements; and implement the rule with a longer effective date. Although most of these alternatives may be a less burdensome alternative to the rule, the Commission determines that none of the alternatives would adequately reduce the risk of deaths and injuries associated with APBRs that is addressed by the rule while still preserving the product's utility to consumers.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1306

[Docket No. DEA–469]

RIN 1117–AB45

Partial Filling of Prescriptions for Schedule II Controlled Substances

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: On July 22, 2016, the Comprehensive Addiction and Recovery Act of 2016 became law. One provision of the Comprehensive Addiction and Recovery Act of 2016 amended the Controlled Substances Act to allow for the partial filling of prescriptions for schedule II controlled substances under certain conditions. The Drug Enforcement Administration (DEA) is amending its regulations to conform to this statutory provision, as well as to provide direction on gaps not addressed by legislation. DEA will also be amending its regulations to update a cross-reference in a paragraph that will be redesignated with this final rule.

DATES: This final rule is effective August 21, 2023.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 776–3882.

SUPPLEMENTARY INFORMATION:

I. Legal Authority

On July 22, 2016, the President signed the Comprehensive Addiction and Recovery Act (CARA) of 2016 into law as Public Law 114–198. Section 702(a) of the CARA amended 21 U.S.C. 829 of the Controlled Substances Act (CSA) by adding subsection (f) to allow a pharmacist to partially fill a prescription for a schedule II controlled substance under certain conditions.