DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

General Hospital and Personal Use Devices: Renaming of Pediatric Hospital Bed Classification and Designation of Special Controls for Pediatric Medical Crib; Classification of Medical Bassinet

Docket No. FDA-2015-N-0701

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the expected costs associated with this rule are expected to be modest, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This rule establishes special controls for medical bassinets and pediatric medical cribs, and permits prescription use of these devices outside of traditional health care settings. This regulation will also change the name of the classification regulation for pediatric hospital beds to pediatric medical cribs and establish a separate classification regulation for medical bassinets as a class II device. The special control requirements set forth in this rule will clarify safety standards and minimize the risk of injury to pediatric patients, providing reasonable assurance of safety and effectiveness. Additionally, permitting prescription use of medical bassinets and pediatric medical cribs outside of traditional health care settings will benefit pediatric patients who require the specialized care provided by these devices. Costs estimated in this analysis include costs related to the new warning labeling requirements, the prescription use and performance testing for medical bassinets and pediatric medical cribs, as well as physical modification of pediatric cribs. The annual costs are $2,379,400, and include the costs of the warning labels and prescription provision. The cost of performance testing is $3,360 per unit and the cost of modifying a pediatric crib is $1,125 per unit.

II. Regulatory Impact Analysis

A. Objective of the Rule

Pediatric hospital beds (21 CFR 880.5140) are classified as class II, 510(k) exempt medical devices intended for the treatment, care, or diagnosis of diseases or illnesses of pediatric patients. In this rule, FDA plans to amend § 880.5140 by revising the identification and establishing special controls for pediatric medical cribs. This rule will also change the name of the classification regulation from “pediatric hospital bed” to “pediatric medical crib,” and place medical bassinets, previously under the pediatric hospital beds classification regulation, into a

separate classification regulation as a class II, 510(k) exempt device, subject to its own special controls.

Pediatric medical cribs contain a drop-side rail design that includes movable and latchable side and end rails. The Consumer Product Safety Commission (CPSC) issued a final rule prohibiting the use of the drop-side rail design for non-medical cribs in consumer households that became effective on June 28, 2011 (December 28, 2010, 75 FR 81766). CPSC's rule established new standards for full-size and non-full-size cribs used for non-medical purposes, which effectively prohibit the manufacture or sale of cribs for non-medical purposes with a drop-side rail design in households, child care facilities, family child care homes, and places of public accommodation. This same rule became effective for child care facilities, family child care homes, and places of public accommodation on December 28, 2012 (75 FR 81766). CPSC's rule was established in response to infant deaths that occurred when the side rail of a crib used for non-medical purposes detached or disengaged. In contrast, there have been no deaths and a few serious injuries reported to FDA associated with pediatric medical cribs, which are made of more durable materials and construction in comparison to cribs used for non-medical purposes. Additionally, FDA has determined that drop-side rails are essential for patient care in hospital settings and even outside of traditional health care settings to allow parents and care givers easy access to their patients in order to perform both routine and emergency medical procedures. To address concerns raised by CPSC's reports on consumer drop-side rail cribs and account for the medical need of this device, FDA is establishing special controls and requiring a prescription for this device when used outside of traditional health care setting. Thus, FDA has determined that cribs with drop-side rail designs may remain on the market when intended for medical use, and can be used outside of traditional health care settings through prescription use

only. In addition, this rule adds specific special controls for medical bassinets to mitigate health risks such as tipping of the device and crazing of the plastic basket or bed component. Regulation of medical bassinets under a separate regulation would also allow for more targeted post market surveillance for this device.

B. Benefits

FDA's Registration and Listing database identifies 39 manufacturers of medical cribs and bassinets. FDA has reviewed the safety standards of several large pediatric crib and bassinet manufacturers in order to determine the compliance burden associated with the special controls. The Agency concludes that many of the special controls in this rule are consistent with current industry practice among many pediatric medical crib and bassinet manufacturers. The special control requirements that are not currently practiced are the warning labeling requirements for both devices. The special controls will clarify for manufacturers the safety standards and help minimize the risk of injury to pediatric patients. The beneficial features of medical bassinets are portability, ease of cleaning, and, when it is made of a clear material, the ability to see the baby from all sides. The special controls will require bassinet manufacturers to place warning labels on two sides of the device. The warning label is intended to educate the user to take precautions to prevent tipping of the device, which may be caused by unlatched drawers, dislodged wheels, or too much weight on the shelves. The Agency has not received any reports of death or serious injury related to medical bassinets, although there have been a small number of reports of malfunctioning casters, which may cause device tipping. The benefits of the new warning label are not readily quantifiable, but it is expected to reduce the risk of the bassinet from tipping or other user error and thus, reduce potential injury to pediatric patients.

The provision allowing for the use of pediatric medical cribs and bassinets outside of traditional health care settings will benefit pediatric patients who require the specialized care provided by these devices outside of traditional health care settings. Due to the CPSC rule regarding cribs used for non-medical purposes, consumers and child care facilities will be restricted from using cribs with a drop-side rail design. This final rule will allow consumers and child care facilities to utilize the pediatric medical cribs and bassinets if they are prescribed by a health care professional.

The warning label requirement for medical cribs would reduce the risk of head and limb entrapment, pinching, lacerations and crushing of a pediatric patient and as well as harm to the adult user. The special controls regarding the mechanical structure of pediatric medical cribs are intended to minimize the risk of injury, including entrapment or strangulation of pediatric patients. The spacing specifications of the side rail components are designed to prevent head or neck entrapment and strangulation incidents in which infants may slip between the openings of the slats, and the performance testing requirements are designed to ensure the side rail latches of pediatric medical cribs will perform as intended and remain secure when the latches are engaged. The special control requiring specific height of the rails and end panels may prevent falls and/or escapes by the patient. Also, by having pediatric medical crib manufacturers use materials that are appropriate for the conditions of use and allow for proper sanitation, these special controls help mitigate surface defects that can cause injury to the patient.

Additionally, the mattress size standards for mattresses used in pediatric medical cribs are intended to reduce the risk of significant gaps between the mattress and the device structure, which could potentially create an entrapment hazard. The flammability standard for these mattresses is intended to reduce deaths and injuries related to mattress fires, particularly those

initially ignited by open flame sources such as lighters, candles, and matches. Although the practices in most of the special controls are believed to be followed by almost all manufacturers of products currently on the market, the special controls will reinforce safety standards for such manufacturers and ensure that other manufacturers and manufacturers of new products adhere to the same safety standards.

C. Costs

The economic impact of this regulation is determined primarily by whether manufacturers currently comply with the special control requirements. FDA is aware that many manufacturers of pediatric medical cribs and medical bassinets registered with the FDA currently conform to the risk mitigations and structural requirements that are being finalized as special controls. Additionally, the renaming of pediatric medical cribs and re-designation in the CFR for medical bassinets and the remaining devices under the pediatric hospital bed classification are administrative in nature, and are not expected to result in any cost burdens. The special controls that are not currently practiced by industry, of which FDA is aware, are the warning labeling and the performance testing requirements. We also estimate costs related to the prescription use of pediatric medical cribs and bassinets and the physical modification of pediatric cribs.

The new warning labeling requirements for medical bassinets and cribs will apply to manufacturers of these devices. If manufacturers add labels to the devices at the time of production, the cost burden to manufacturers will be minimized. Although we do not have direct estimates of labeling costs for these devices, the best estimate of these costs is derived from FDA's labeling cost model. Because FDA requires specific language and format of the labels, we consider this to be a minor labeling change that will not require label design, market tests, or analytical tests. Labeling costs will include labor and material, and are estimated to be, on

average, approximately $140 per unit. Because this regulation requires that the warning labels be placed on at least two sides of the bassinets and cribs, we multiply the unit labeling cost by a factor of 1.5 to account for the double labeling. This yields a labeling cost of $210 ($140 x 1.5) per unit.

In order to determine the number of bassinets produced per year for medical use, we refer to the number of live births per year as reported by the Center for Disease Control and Prevention (Ref. 1). Using an estimate of 4 million births per year and 11,000 births per day, we estimate that each birth requires an average hospital stay of 3 days. This yields a total supply of approximately 33,000 medical bassinets in the United States. Using an average annual replacement rate of 20 percent for all medical bassinets, we estimate that approximately 6,600 new bassinets will be produced annually and will require new labeling. Applying a $210 per unit labeling cost yields a total annual cost of $1,386,000 ($210 x 6,600) associated with the medical bassinet warning label requirement.

We estimate the number of pediatric medical cribs currently in use as a percentage of total staffed beds in U.S. hospitals. According to the American Hospital Association, there are a total of 786,874 staffed beds in registered community hospitals in the U.S. (Ref. 2). There are approximately 36 million hospital stays in the U.S. annually (Ref. 3). Using data from the Healthcare Cost and Utilization Project, we estimate that approximately 2.25 percent of hospital stays are for children within the age group that would utilize pediatric cribs (Ref. 4). Multiplying this estimate by the total number of staffed hospital beds yields a total supply of approximately 17,700 (786,874 x .0225) pediatric cribs. Using an average annual replacement rate of 20 percent for all hospital pediatric cribs, we estimate that approximately 3,540 new cribs will be produced annually and will require new labeling. Applying the $210 per unit labeling cost

yields a total annual cost of $743,400 ($210 x 3,540) associated with the new medical crib warning label requirement.

The prescription use of pediatric medical cribs and bassinets outside of traditional health care settings may potentially increase Medicaid spending for eligible pediatric patients. According to our review of Healthcare Common Procedure Coding System billing codes for the Medicaid program, currently, States typically offer Medicaid coverage for prescribed rental or purchase of hospital beds and pediatric cribs (Ref. 6). Based on FDA's experience and knowledge of the industry, we expect that the need for prescription would be rare. We estimate that less than 100 prescriptions for pediatric medical cribs or bassinets will be filled annually as a result of this regulation. Medicaid expenditure on pediatric medical cribs and bassinets is estimated to be on average $2,500 per device. This yields a maximum annual total cost of $250,000.

The special controls require performance testing for medical bassinets to reduce the risk of crazing of the plastic basket or bed component. We assume that the performance testing may be conducted as an extension to current product testing and may be performed at the same testing facilities currently utilized by bassinet manufacturers. FDA projects that a maximum of an additional week of testing would be required. The costs associated with the performance testing include the labor costs of mechanical engineers, who typically perform these tests. The mean 2014 hourly wage for mechanical engineers is $41.89, as reported by the Occupational Employment Statistics provided by the Bureau of Labor Statistics (Ref. 5). Applying a multiplier of 2 to adjust for benefits and overhead, hourly labor costs are estimated to be approximately $84. Assuming a 40-hour work week, the total maximum estimated cost for each manufacturer to perform these additional tests is approximately $3,360 per unit. It is uncertain

how many manufacturers do not currently conduct performance testing and would therefore be required to extend current testing practices. However, given the relatively small number of medical bassinet manufacturers, FDA anticipates that even the upper-bound total cost would be modest.

Although it is unlikely that these devices will require physical modification to meet the standards of the special controls in this final rule, there may be manufacturers on the market of which we are unaware that do not conform to the requirements in the special controls. The special controls could have a significant impact on firms that are not currently in compliance with the special control requirements, as their products may require modifications. The special control requirement concerning the mechanical structure of pediatric medical cribs may cause additional costs for manufacturers. We are not able to estimate the actual compliance costs for manufacturers of pediatric medical cribs because such costs may vary by firm size and the amount of modification required. Alternatively, we provide an estimate of the modification cost by using aggregate industry market price information and cost data. The costs associated with these modifications may include the costs associated with product design and testing, labor, material, and production. We use data from the Annual Survey of Manufacturers to calculate aggregate labor and materials costs as a percentage of total sales for manufacturers represented by North American Industry Classification System code 339113 (Ref. 7). The data indicate that labor and materials represent approximately 45 percent of total sales. Allowing market price to represent per unit revenue at the firm level, we estimate the cost of modification to be approximately 45 percent of the average price of a pediatric medical crib. After surveying market prices of pediatric medical cribs, we estimate an average per unit price of $2,500. This yields an average cost of approximately $1,125 per unit to modify a pediatric medical crib to be

in compliance with the special controls. We don't expect there will be a need for modifications, but should it occur we estimate that the total cost would be modest.

III. Regulatory Flexibility Analysis

FDA has examined the economic implications of the final rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. Because the costs associated with this rule are expected to be minimal, we certify that this rule would not impose a significant economic impact on a substantial number of small entities.

IV. References

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