

## MEDICAID EVIDENCE-BASED DECISIONS PROJECT

# Medicaid Coverage of Enclosed Beds

Enclosed beds, also known as safety beds, feature padded walls, mesh canopies with zippered door access, and other modifications to create safe sleep spaces and prevent climbing out of bed or seizure-related falls. These specialized devices are marketed as protecting patients from injury risks, and are often used by children with conditions such as autism spectrum disorder (ASD) or developmental disabilities.





Sources. Beds by George (above); Cubby Beds.

State Medicaid programs noted increasing requests for these beds in recent years, which our literature review and key informant interviews link to rising ASD prevalence, pandemic-related sleep pattern disruptions, and increased marketing of these products through social media. However, evidence supporting the effectiveness of enclosed beds is extremely limited, posing challenges when determining medical necessity and appropriate use of medical equipment versus restraint or convenience devices. Patient safety, restraint prevention, access considerations, and inconsistent pricing and reimbursement policies are principal issues that Medicaid programs must consider.

Medicaid Evidence-based Decisions Project (MED) members in the durable medical equipment (DME) workgroup requested this tool to explain the benefits and risks of using enclosed beds for qualifying conditions and populations, summarize current medical necessity and coverage criteria across

Medicaid programs, and highlight any evidence gaps or policy considerations needed to guide decision making around claims and regulations. This tool is based on the MED report, *Enclosed Beds and Associated Technologies*,<sup>1</sup> which is available through the MED clearinghouse. Methods used for developing this tool can be found in <u>Appendix A</u>.

## **EVIDENCE FOR EFFECTIVENESS AND HARMS OF ENCLOSED BEDS**

The evidence for the effectiveness and safety of enclosed beds is extremely limited. Only 1 tangentially relevant randomized controlled trial was identified, which found improved perception of enclosed beds compared with standard restraints among relatives and some hospital staff for adult patients, but no differences in agitation, length of stay, or medication use.<sup>2</sup> No studies on enclosed bed use in home settings or for children or youth were found. Due to this lack of evidence, clinical guidelines do not include enclosed beds in recommendations for managing sleep issues, wandering, or fall risks in people with neurodevelopmental disorders.<sup>3-14</sup> Instead, guidelines recommend behavioral therapy and melatonin for improving sleep, and using locks on doors or windows to prevent wandering.<sup>14</sup> Several systematic reviews emphasize the lack of evidence for most sleep interventions in these populations, with melatonin and behavioral approaches being the most studied.<sup>15-20</sup>

Given the limited research, Medicaid and commercial insurance policies on enclosed bed coverage largely cite other payer policies, FDA guidance on hospital bed safety, and in a few cases, the single RCT mentioned above.<sup>21-25</sup> Some policies also reference studies on general sleep issues in autism that do not specifically evaluate enclosed beds.<sup>25-29</sup> This highlights the overall scarcity of high-quality evidence to inform policy decisions regarding enclosed bed use and coverage.

#### **ENCLOSED BED COVERAGE ACROSS MEDICAID PROGRAMS**

Medicaid is the primary payer for enclosed beds in the US, with commercial payers a distant second, according to enclosed bed manufacturers Beds by George and Cubby.<sup>30</sup> Many children who need these beds come from low-income households or have medical conditions that qualify them for Medicaid waivers or programs.<sup>30,31</sup> Key coverage pathways include home and community-based waivers and the Katie Beckett option.<sup>30,31</sup>

## **Medical Necessity and Qualifying Conditions**

Across the Medicaid and commercial policies reviewed, common qualifying conditions for enclosed beds are often traumatic brain injury, cerebral palsy, seizure disorders, developmental delays, and severe behavioral disorders. <sup>22,23,32-36</sup> Commercial plans often mirror Medicaid policies but may have additional qualifying conditions such as neurological disorders causing disorientation, vertigo, or uncontrolled movements. <sup>37-39</sup> While rarely listed as a qualifying condition, <sup>22,23,32-39</sup> ASD may fall under broader categories such as behavioral disorders or developmental disabilities.

Diagnosis alone does not guarantee qualification; patient assessment must demonstrate specific needs can be addressed by an enclosed bed.<sup>22,23,32-36</sup> Some Medicaid programs and commercial payers assess needs case-by-case without specifying diagnoses.<sup>25,40-46</sup> Other policies emphasize enclosed beds are not considered medically necessary for preventing injuries from seizure activity or self-injurious behaviors. 22,24

A related ethical issue is that enclosed beds can be misused as a form of restraint. <sup>30,40,47</sup> This inappropriate use occurs when caregivers prioritize their own needs or preferences over the individual's autonomy.<sup>47</sup> Instead of addressing the underlying reasons for wandering behavior, some caregivers may resort to confining the person to prevent nighttime roaming. 30,40,47 This practice allows the caregiver to rest uninterrupted, but raises ethical concerns about restricting personal freedom and potentially exacerbating the child's distress. 30,40,47 We discuss state Medicaid program strategies to ensure enclosed beds are not used as restraints below.

## Strategies to Avoid Use of Beds as Restraints

Medicaid programs emphasize that enclosed beds should not be used for<sup>25,35,45,46</sup>:

- Restraint
- Discipline
- Caregiver needs and preferences

Clinical criteria used by state Medicaid programs and commercial plans to deter inappropriate USe22-25,34,35,40,42,44-46,48

- Specific measures to prevent the use of enclosed beds as restraints
- Require proof of actual injury before approval
- Mandate that underlying behavioral conditions are addressed first
- Limit use to nighttime or short rest periods

Requiring design requirements to reduce isolation<sup>25</sup>:

• Slats for visual and auditory access

## Challenges<sup>30</sup>:

- Difficulty monitoring home use
- Total prevention of misuse may not be possible

## Adverse Events Associated With Enclosed Beds

Enclosed beds have been associated with various adverse events, with most involving material separation and structural integrity issues. 49-71 Notable incidents include ingestion of disassembled parts (Cubby beds),<sup>69</sup> falls due to rail malfunctions (Pedicraft),<sup>53</sup> patient entrapment, a fractured ankle (Beds by George), 70,71 and a possible broken finger caused by material separation (Posey beds). 58 Significantly, enclosed beds have been subject to 2 Class 1 recalls, which are the most serious type of recall issued when there is a reasonable probability that product use or exposure will cause serious injury or death.<sup>72</sup> The recalls were for Cubby beds in 2022 following a fatal entrapment incident, leading to enhanced safety instructions, 73 and Vail Products in 2005 due to multiple entrapments resulting in severe injuries or death, ultimately leading to the cessation of manufacturing.<sup>74-76</sup>

## REIMBURSEMENT POLICIES FOR ENCLOSED BEDS

## Coding

The Centers for Medicare & Medicaid Services (CMS) has assigned Healthcare Common Procedure Coding System (HCPCS) code E0316 for safety enclosure frames or canopies used with hospital beds.<sup>77</sup> However, no specific HCPCS codes exist for standalone enclosed beds.<sup>77</sup> State Medicaid programs often use codes E0328, E0329, and E1399 for reimbursement. 40,41,78 Georgia Medicaid created a modified E0328 code (E0328 U1) to better identify and reimburse standalone enclosed beds.41

#### **Efforts to Obtain a Unique HCPCS Code**

The industry currently is working to strengthen evidence of medical necessity for enclosed beds to obtain a unique HCPCS code.<sup>30</sup> The CEO of Cubby beds, arguing current codes are inadequate, initiated a qualitative study with caregivers and clinicians, a systematic literature review, and a health economics and outcomes research study to persuade CMS to create a HCPCS code for enclosed beds.<sup>30</sup>



Source. Beds By George.

## Reimbursement Strategies

The costs for enclosed beds range from \$3,789 to \$19,438, with potential additional markups by DME suppliers. 77,79,80 Medicaid reimbursement strategies vary across states. Georgia Medicaid's modified E0328 U1 code sets reimbursement limits at the lesser of the manufacturer's suggested retail price (MSRP), invoice price, or a combined maximum of \$8,581.60 (complete bed \$7,735.20 plus a 4-side, high-density foam cover at \$846.40).<sup>41</sup> Minnesota uses a methodology of MSRP minus 20% or invoice plus 20%, while Massachusetts Medicaid pays actual acquisition cost plus 30%.<sup>24</sup> Uniquely, Massachusetts Medicaid code K0739 reimburses for labor costs to install enclosed beds in an enrollee's home at \$46.33 per hour.<sup>48</sup> This approach ensures Medicaid recipients can access these beds by covering both the cost of the beds and the installation.<sup>30</sup>

## **CONCLUSION**

The use of enclosed pediatric beds for children with conditions such as ASD or developmental disabilities presents a policy challenge. Despite growing demand, there is limited evidence on the clinical effectiveness and safety of these beds. The single randomized controlled trial conducted in a hospitalized adult population, suggests enclosed beds may be perceived as a humane and safe restraint alternative. The lack of robust evidence in pediatric settings and absence of cost-outcome data represent significant knowledge gaps.

Some Medicaid programs have begun to respond to the increasing requests for enclosed beds through rigorous prior authorization processes. These processes aim to confirm medical necessity and prevent inappropriate use; however, the scarcity of evidence makes it challenging to assess claims effectively. Key issues are poor documentation quality and difficulty differentiating between behavioral and medical needs.

The rising demand for enclosed beds, particularly for children with ASD, appears to be driven by increased ASD prevalence, pandemic-related sleep disruptions, and manufacturer marketing. This underscores the need for more studies to track outcomes and adverse events following prescription.

State Medicaid programs may want to consider:

- Implementing enclosed bed tracking programs to gather real-world data on outcomes and adverse events.
- Developing standardized submission checklists and increasing reviewer training to improve consistency in the review process.
- Consider having either in-house or external clinician review claims for enclosed beds and their accessories like the technology hub used for Cubby beds.
- Reviewing denial rates and reasons to identify potential gaps in medical necessity criteria.
- Producing clear policies on accessory coverage to streamline the review process.
- Systematically tracking patient outcomes and use patterns.
- Considering reimbursement for ancillary costs such as delivery and installation labor.

As requests for enclosed beds continue to increase, more data is needed to guide evidence-based policymaking. Future research should prioritize safety considerations and focus on distinguishing between medical necessity and convenience use. Clinicians, caregivers, and payers should all be invested in optimizing other means of assuring safety and optimal sleep patterns. By addressing these challenges, policymakers can ensure that children who truly need these specialized beds can access them, while also safeguarding against potential misuse or harm.

#### **REFERENCES**

- Dickson V, Vintro A, King VJ, Evans A. Enclosed beds and associated technologies. Portland, OR: Oregon Health & Science University; 2024.
- Nawaz H, Abbas A, Sarfraz A, et al. A randomized clinical trial to compare the use of safety net enclosures with standard restraints in agitated hospitalized patients. J Hosp Med. 2007;2(6):385-393. doi: 10.1002/jhm.273.
- Autism Speaks. Parent seeks help for young child's nighttime wandering. https://www.autismspeaks.org/expert-opinion/parentseeks-help-young-childs-nighttime-wandering. Accessed December 18, 2023.
- Autism Speaks. Sleep strategies for children with autism. https://www.autismspeaks.org/sites/default/files/2018-08/Sleep%20Tool%20Kit.pdf. Accessed December 18, 2023.
- Elias ER, Murphy NA, Liptak GS, et al. Home care of children and youth with complex health care needs and technology dependencies. Pediatrics. 2012;129(5):996-1005. doi: 10.1542/peds.2012-0606.
- Huang P, Durbin D. Promoting safety in children with disabilities. UpToDate; 2023; https://www.uptodate.com/contents/promoting-safety-inchildren-withdisabilities?sectionName=Prevention%20of%20elopement &search=sleep%20and%20autism&topicRef=608&anchor= H15&source=see link. Accessed January 10, 2024.
- 7. Hyman SL, Levy SE, Myers SM, et al. Identification, evaluation, and management of children with autism spectrum disorder. Pediatrics. 2020;145(1):e20193447. doi: 10.1542/peds.2019-3447.
- Ivanenko A, Chervin R, Eichler A. Sleep in children and adolescents with attention deficit hyperactivity disorder. UpToDate; 2023; https://www.uptodate.com/contents/sleep-in-childrenand-adolescents-with-attention-deficit-hyperactivitydisorder?search=sleep%20disorder&source=search\_result\_ &selectedTitle=8~150&usage type=default&display rank= 8. Accessed December 18, 2023.
- Noritz G, Davidson L, Steingass K. Providing a primary care medical home for children and youth with cerebral palsy. Pediatrics. 2022;150(6):e2022060055. doi: 10.1542/peds.2022-060055.
- 10. Pliszka S. Practice parameter for the assessment and treatment of children and adolescents with attentiondeficit/hyperactivity disorder. J Am Acad Child Adolesc

- Psychiatry. 2007;46(7):894-921. doi: 10.1097/chi.0b013e318054e724.
- 11. Quigg M, Pavlova MK, Buchanan GF. Proceedings of the sleep and epilepsy workshop: introduction. Epilepsy Curr. 2021;21(3):15357597211004551. doi: 10.1177/15357597211004551.
- 12. Siegel M, McGuire K, Veenstra-VanderWeele J, et al. Practice parameter for the assessment and treatment of psychiatric disorders in children and adolescents with intellectual disability (intellectual developmental disorder). J Am Acad Child Adolesc Psychiatry. 2020;59(4):468-496. doi: 10.1016/j.jaac.2019.11.018.
- 13. Volkmar F, Siegel M, Woodbury-Smith M, King B, McCracken J, State M. Practice parameter for the assessment and treatment of children and adolescents with autism spectrum disorder. J Am Acad Child Adolesc Psychiatry. 2014;53(2):237-257. doi: 10.1016/j.jaac.2013.10.013.
- 14. Williams Buckley A, Hirtz D, Oskoui M, et al. Practice guideline: treatment for insomnia and disrupted sleep behavior in children and adolescents with autism spectrum disorder. Neurology. 2020;94(9):392-404. doi: 10.1212/wnl.0000000000009033.
- 15. Boyle MA, Adamson RM. Systematic review of functional analysis and treatment of elopement (2000-2015). Behav Anal Pract. 2017;10(4):375-385. doi: 10.1007/s40617-017-0191-y.
- 16. Cortese S, Wang F, Angriman M, Masi G, Bruni O. Sleep disorders in children and adolescents with autism spectrum disorder: diagnosis, epidemiology, and management. CNS Drugs. 2020;34(4):415-423. doi: 10.1007/s40263-020-00710-y.
- 17. Esposito D, Belli A, Ferri R, Bruni O. Sleeping without prescription: management of sleep disorders in children with autism with non-pharmacological interventions and over-the-counter treatments. Brain Sciences. 2020;10(7). doi: 10.3390/brainsci10070441.
- 18. Mammarella V, Orecchio S, Cameli N, et al. Using pharmacotherapy to address sleep disturbances in autism spectrum disorders. Expert Rev Neurother. 2023;23(12):1261-1276. doi: 10.1080/14737175.2023.2267761.
- 19. T-Pederson C, Reisert H, Adesman A. Wandering behavior in children with autism spectrum disorder and other developmental disabilities. Curr Opin Pediatr. 2021;33(4):464-470. doi: 10.1097/mop.0000000000001038.

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- Wiggs L, France K. Behavioural treatments for sleep problems in children and adolescents with physical illness, psychological problems or intellectual disabilities. *Sleep Med Rev.* 2000;4(3):299-314. doi: 10.1053/smrv.1999.0094.
- Centers for Disease Control and Prevention. Data & statistics on autism spectrum disorder. 2023; <a href="https://www.cdc.gov/ncbddd/autism/data.html">https://www.cdc.gov/ncbddd/autism/data.html</a> Accessed January 23, 2024.
- Illinois Department of Healthcare and Family Services.
   Pediatric specialty beds criteria 2023;
   <a href="https://hfs.illinois.gov/medicalproviders/mpac/psbcriteria.html">https://hfs.illinois.gov/medicalproviders/mpac/psbcriteria.html</a>. Accessed December 30, 2023.
- Iowa Department of Health and Human Services. Safety beds. 2023; <a href="https://hhs.iowa.gov/media/323/download?inline">https://hhs.iowa.gov/media/323/download?inline</a>. Accessed December 30, 2023.
- 24. Minnesota Department of Health. Hospital beds. 2023; https://www.dhs.state.mn.us/main/idcplg?ldcService=GET DYNAMIC CONVERSION&RevisionSelectionMethod=La testReleased&dDocName=DHS16 152895. Accessed December 28, 2023.
- The Department of Vermont Health Access. Special needs protective beds. 2022;
   https://dvha.vermont.gov/sites/dvha/files/documents/providers/Forms/special%20needs%20protective%20bed%20criteria%20for%20web.pdf. Accessed January 23, 2024.
- Cubby Beds. Technology hub 2023; <a href="https://cubbybeds.com/products/technology-hub-2">https://cubbybeds.com/products/technology-hub-2</a>.
   Accessed January 31, 2024.
- 27. Mannion A, Leader G. Sleep problems in autism spectrum disorder: a literature review. *Rev J Autism Dev Disord*. 2014;1(2):101-109. doi: 10.1007/s40489-013-0009-y.
- Taylor MA, Schreck KA, Mulick JA. Sleep disruption as a correlate to cognitive and adaptive behavior problems in autism spectrum disorders. *Res Dev Disabil*. 2012;33(5):1408-1417. doi: 10.1016/j.ridd.2012.03.013.
- Veatch OJ, Maxwell-Horn AC, Malow BA. Sleep in autism spectrum disorders. Curr Sleep Med Rep. 2015;1(2):131-140. doi: 10.1007/s40675-015-0012-1.
- 30. Dickson V, Vintro A, King V, Evans A. *Enclosed beds and associated technologies*. Portland, OR: Oregon Health & Science University; 2024.
- 31. Musumeci M, Watts M, Ammula M, Burns A. Medicaid financial eligibility in pathways based on old age or disability in 2022: Findings from a 50-state survey. 2022; https://www.kff.org/report-section/medicaid-financial-

- <u>eligibility-in-pathways-based-on-old-age-or-disability-in-2022-findings-from-a-50-state-survey-appendix/.</u>
  Accessed January 7, 2024.
- Caresource. Safety beds. 2023; <a href="https://www.caresource.com/documents/medicaid-ga-policy-medical-mm-1456-20230701.pdf">https://www.caresource.com/documents/medicaid-ga-policy-medical-mm-1456-20230701.pdf</a>. Accessed December 20, 2023.
- Humana Healthy Horizon in Louisiana. Hospital beds clinical coverage policy. 2023; https://ldh.la.gov/assets/medicaid/MCPP/11.28.22/2/165
   HHH UM 15 Hospital Beds Clinical Coverage Policy.p df. Accessed December 28, 2023.
- 34. Indiana Medicaid. Durable and home medical equipment and supplies. 2023;
  <a href="https://www.in.gov/medicaid/providers/files/modules/durable-and-home-medical-equipment-and-supplies.pdf">https://www.in.gov/medicaid/providers/files/modules/durable-and-home-medical-equipment-and-supplies.pdf</a>.

  Accessed January 23, 2024.
- Rhode Island Executive Office of Health and Human Services. Hospital beds. 2023; <a href="https://eohhs.ri.gov/ProvidersPartners/ProviderManualsGuidelines/MedicaidProviderManual/DME/CoverageGuidelinesforDurableMedicalEquipment.aspx">https://eohhs.ri.gov/ProvidersPartners/ProviderManualsGuidelines/MedicaidProviderManual/DME/CoverageGuidelinesforDurableMedicalEquipment.aspx</a>. Accessed December 28, 2023.
- UnitedHealthcare. Beds and mattresses. 2023; <a href="https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medicaid-comm-plan/ne/beds-mattresses-ne-cs.pdf">https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medicaid-comm-plan/ne/beds-mattresses-ne-cs.pdf</a>. Accessed December 31, 2023.
- Anthem. Hospital beds and accessories. 2023; <a href="https://www.anthem.com/dam/medpolicies/abcbs/active/guidelines/gl-pw-a053641.html">https://www.anthem.com/dam/medpolicies/abcbs/active/guidelines/gl-pw-a053641.html</a>. Accessed December 20, 2023.
- Centene. Durable medical equipment and orthotics and prosthetics guidelines. 2023;
   <a href="https://www.healthnet.com/content/dam/centene/policies/clinical-policies/CP.MP.107.pdf">https://www.healthnet.com/content/dam/centene/policies/clinical-policies/CP.MP.107.pdf</a>. Accessed December 30, 2023.
- Molina Healthcare. Enclosed bed systems. 2023; https://www.molinahealthcare.com/~/media/Molina/Publicw/Enclosed/20Bed/20Systems.pdf.

   Accessed December 20, 2023.
- California Department of Social Services. Durable medical equipment manual. 2023;
   <a href="https://mcweb.apps.prd.cammis.medi-cal.ca.gov/assets/58152677-9614-44AB-AAOA-1F3F04123E7D/duraother.pdf?access-token=6UvVkRRfB-yXTZEWIh8j8QaYyIPyP5ULO">https://mcweb.apps.prd.cammis.medi-cal.ca.gov/assets/58152677-9614-44AB-AAOA-1F3F04123E7D/duraother.pdf?access-token=6UvVkRRfB-yXTZEWIh8j8QaYyIPyP5ULO</a>. Accessed December 27, 2023.

- 41. Georgia Medicaid. Durable medical equipment manual. 2023;
  - https://www.mmis.georgia.gov/portal/PubAccess.Provider %20Information/Provider%20Manuals/tabld/18/Default.a spx. Accessed December 17, 2023.
- 42. Masshealth. Guidelines for medical necessity determination for hospital beds. 2010; https://www.mass.gov/doc/hospital-beds/download. Accessed December 31, 2023.
- 43. MassHealth. Masshealth prescription and medical necessity review form for hospital beds. 2023; https://www.mass.gov/doc/medical-necessity-reviewform-for-hospital-beds-0/download. Accessed January 25, 2024.
- 44. Michigan Department of Health and Human Services. Medicaid provider manual. 2023; https://www.mdch.state.mi.us/dchmedicaid/manuals/MedicaidProviderManual.pdf. Accessed December 6, 2023.
- 45. North Carolina Department of Health and Human Services. Physical rehabilitation equipment and supplies. 2023; https://medicaid.ncdhhs.gov/5a-1-physical-rehabilitationequipment-and-supplies/download?attachment. Accessed December 28, 2023.
- 46. Texas Secretary of State. Enclosed beds. 2023; https://texreg.sos.state.tx.us/public/readtac\$ext.TacPage? sl=R&app=9&p dir=&p rloc=&p tloc=&p ploc=&pg=1&p t ac=&ti=26&pt=1&ch=565&rl=35. Accessed December 27, 2023.
- 47. Healthy Blue. Enclosed bed systems (safety enclosure frame or canopy) for hospital beds 2023; https://www.myhealthtoolkit.com/web/public/brands/me dicalpolicyhb/external-policies/enclosed-bed-systemssafety-enclosure-framecanopy-for-hospitalbeds/?utm\_source=textcortex&utm\_medium=zenochat.
- 48. Masshealth. Masshealth prescription and medical necessity review form for hospital beds. 2021; https://www.mass.gov/doc/medical-necessity-reviewform-for-hospital-beds-0/download. Accessed December 31, 2023.
- 49. US Food and Drug Administration. Maude adverse event report: sensory medical inc cubby bed enclosed canopy https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi\_id=16066387&pc=OYS. Accessed December 18, 2023.
- 50. US Food and Drug Administration. Maude adverse event report: sensory medical inc cubby bed enclosed canopy bed. 2022;

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=16066376&pc=OYS. Accessed December 19, 2023.
- 51. US Food and Drug Administration. Maude manufacturer and user facility device experience. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/results.cfm. Accessed December 18, 2023.
- 52. US Food and Drug Administration. Maude adverse event report: tidi products posey bed 8070. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=16287517&pc=OYS. Accessed December 15, 2023.
- 53. US Food and Drug Administration. Maude adverse event report: pedicraft. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=9823668&pc=NZG. Accessed December 15, 2023.
- 54. US Food and Drug Administration. Maude adverse event report: posey products 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=12528140&pc=OYS. Accessed December 15, 2023.
- 55. US Food and Drug Administration. Maude adverse event report: tidi products. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=12514999&pc=OYS. Accessed December 16, 2023.
- 56. US Food and Drug Administration. Maude adverse event report: tidi products Ilc posey bed. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=10477144&pc=OYS. Accessed December 15, 2023.
- 57. US Food and Drug Administration. MAUDE adverse event report: posey products. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=9795873&pc=OYS. Accessed December 15, 2023.
- 58. US Food and Drug Administration. Maude adverse event report: posey products 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=9330523&pc=OYS. Accessed Decmber 17, 2023.
- 59. US Food and Drug Administration. MAUDE adverse event report: posey products. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=8579234&pc=OYS. Accessed December 16, 2023.

- 60. US Food and Drug Administration. Maude adverse event report: posey products 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=8314104&pc=OYS. Accessed December 17, 2023.
- 61. US Food and Drug Administration. Maude adverse event report: cubby bed. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=16067619&pc=OYS. Accessed December 17, 2023.
- 62. US Food and Drug Administration. MAUDE adverse event report: Cubby Bed. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=16066374&pc=OYS. Accessed December 16, 2023.
- 63. US Food and Drug Administration. Maude adverse event report: cubby bed. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=16067624&pc=OYS. Accessed December 20, 2023.
- 64. US Food and Drug Administration. Maude adverse event report: cubby bed. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=16067631&pc=OYS. Accessed December 18, 2023.
- 65. US Food and Drug Administration. Maude adverse event report:cubby bed. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=16067621&pc=OYS. Accessed Decmber 18, 2023.
- 66. US Food and Drug Administration. Maude adverse event report: cubby bed. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=16067609&pc=OYS. Accessed December 28, 2023.
- 67. US Food and Drug Administration. Maude adverse event report: cubby bed. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=16066390&pc=OYS. Accessed December 15, 2023.
- 68. US Food and Drug Administration. MAUDE adverse event report: Cubby Bed. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=16066376&pc=OYS. Accessed December 18, 2023.
- 69. US Food and Drug Administration. Maude adverse event report: cubby technology hub. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma

- ude/detail.cfm?mdrfoi id=16001108&pc=OYS. Accessed December 19, 2023.
- 70. US Food and Drug Administration. MAUDE adverse event report: Beds By George. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=8569260&pc=FNJ. Accessed December 19, 2023.
- 71. US Food and Drug Administration. MAUDE adverse event report: Beds By George. 2023; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfma ude/detail.cfm?mdrfoi id=15553736&pc=OYS. Accessed December 22, 2023.
- 72. US Food and Drug Administration. Recalls, corrections and removals 2023; https://www.fda.gov/medicaldevices/postmarket-requirements-devices/recallscorrections-and-removals-devices. Accessed January 29, 2024.
- 73. US Food and Drug Administration. Class 1 device recall cubby bed. 2022; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres /res.cfm?id=192277. Accessed Decmber 30, 2023.
- 74. US Food and Drug Administration. Class 1 device recall vail 500 enclosed bed system. 2005; https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres /res.cfm?id=39027. Accessed December 30, 2023.
- 75. FDAnews. Vail issues recall of enclosed bed systems. 2005; https://www.fdanews.com/articles/73683-vail-issuesrecall-of-enclosed-bed-systems. Accessed December 28, 2023.
- 76. Federal Institute of Medical Devices. FDA advice concerning enclosed bed systems manufactured by vail products. 2005; https://www.bfarm.de/SharedDocs/Risikoinformationen/ Medizinprodukte/EN/FDA-advice Enclosed-Bed-Systems\_Vail-Products.html?nn=708446. Accessed February 16, 2024.
- 77. ECRI Institute. Clinical utility of specialty beds for children with special needs. 2019; https://www.ecri.org/searchresults/member-preview/specialreports/pages/27833. Accessed February 3, 2024.
- 78. Centers for Medicare and Medicaid Services. Hospital beds. 1989: https://www.cms.gov/medicare-coveragedatabase/view/ncd.aspx?NCDId=227. Accessed January 7, 2024.
- 79. Adaptive Mall. Beds by Geoge. 2023; https://www.adaptivemall.com/ssearch/search/index/?g= beds+by+george. Accessed January 29, 2024.

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80. Cubby Beds. Cubby beds. 2023; <a href="https://cubbybeds.com/products/cubby-beds-private-pay">https://cubbybeds.com/products/cubby-beds-private-pay</a>. Accessed January 29, 2024.

#### **APPENDIX A**

#### Methods

To identify evidence on enclosed bed benefits, harms, and policies, researchers from the Center for Evidence-based Policy (Center) conducted searches of Ovid MEDLINE, and the Cochrane Library. Studies included for evidence were assessed for risk of bias. We reviewed published payer policies from 12 state Medicaid programs (California, Georgia, Illinois, Indiana, Iowa, Massachusetts, Michigan, Minnesota, North Carolina, Rhode Island, Texas, and Vermont) and commercial policies published by Aetna, Anthem, CareSource, Centene, Cigna, Driscoll Health Plan, Highmark, Humana, Molina, Priority Health, and UnitedHealthcare. We also summarized adverse event data from the US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database between 2018–2023.

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