Pediatric Drug and Device Laws: Reauthorization Implementation Timeline

Food and Drug Administration Safety and Innovation Act
Enacted July 9, 2012

American Academy of Pediatrics
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DATE	DEADLINES AND EFFECTIVE DATES
July 9, 2012	President Obama signs *Food and Drug Administration Safety and Innovation Act* (PL 112-144). Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA) become a permanent part of the Food, Drug, and Cosmetic Act. National Institutes of Health BPCA program reauthorized through October 1, 2017. Pediatric humanitarian device exemption (HDE) profit incentive and Pediatric Device Consortia program reauthorized through October 1, 2017. Most amendments to BPCA and PREA take immediate effect, including: ▪ Requirement for written requests to address neonates ▪ Requirement for a neonatologist to sit on the Pediatric Review Committee ▪ Requirement for the Office of Pediatric Therapeutics to hire a neonatologist to assist the agency in applying BPCA and PREA to neonatal populations ▪ Streamlined referral process for uncompleted BPCA studies ▪ Ability for sponsors to request a PREA deferral extension for good cause ▪ Requirement for the Pediatric Review Committee to review deferral extension requests ▪ Authority for the FDA to require any necessary pediatric safety information on certain generic drug labels ▪ Modifications to PREA annual review contents and new FDA publication timeframe
December 31, 2012	**Pediatric Device Tracking Rule** FDA must issue a proposed rule implementing the pediatric device tracking rule from the *Pediatric Medical Device Safety and Improvement Act of 2007*.
January 5, 2013	**Pediatric Study Plans** • All applications subject to PREA and submitted to FDA on or after this date must submit a pediatric study plan at the end of Phase 2 or another appropriate time agreed to by FDA, notwithstanding the promulgation of regulations or the issuance of guidance. • The Pediatric Review Committee shall review pediatric study plans and any significant amendments to such plans. **Deadline for Submission of Certain Deferral Extensions** Deadline for sponsors to submit deferral extension requests for any expired PREA deferral or any PREA deferral that will expire before April 5, 2013.
April 5, 2013	**Issuance of Non-Compliance Letters** FDA must issue non-compliance letters to any sponsors with expired PREA deferrals unless a deferral extension request has been received.

DATE	DEADLINES AND EFFECTIVE DATES
July 9, 2013	**Proposed Rule on Pediatric Study Plans** FDA must publish a proposed rule outlining pediatric study plan content and timing. **Response to Certain Deferral Extension Requests** FDA must respond to all deferral extension requests received for deferrals that expired before April 5, 2013. **PeRC Operating Procedures** FDA shall publish internal standard operating procedures outlining Pediatric Review Committee re-review of modified pediatric study plans and written requests.
December 31, 2013	**Pediatric Device Tracking Final Rule** FDA must issue a final rule implementing the pediatric device tracking rule from the *Pediatric Medical Device Safety and Improvement Act of 2007*.
January 9, 2014	**Meeting on Therapies for Pediatric Rare Diseases** Deadline for FDA to hold a meeting on accelerating development of therapies for pediatric rare diseases. FDA must publish a related strategic plan 180 days after the meeting.
July 9, 2015	**Data Transparency** FDA must release on its website data reviews of BPCA studies submitted between January 4, 2002 and September 27, 2007 that resulted in both the awarding exclusivity and a label change.
January 11, 2016	**BPCA/PREA Stakeholder Feedback Opportunity** Last day for FDA to solicit stakeholder feedback for BPCA and PREA report 180 days before publication deadline.
July 9, 2016	**BPCA/PREA Report Due** FDA must publish and submit to Congress a report on BPCA and PREA (and must do so every five years thereafter).
October 1, 2017	**Expiring Authorizations** Authorization for NIH BPCA program expires HDE profit incentive expires Authorization for Pediatric Device Consortia expires